**OMNIBUS SOLICITATION OF THE
NATIONAL INSTITUTES OF HEALTH,
CENTERS FOR DISEASE CONTROL AND PREVENTION,
AND FOOD AND DRUG ADMINISTRATION FOR**

SMALL BUSINESS INNOVATION RESEARCH (SBIR)

AND

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR)

GRANT APPLICATIONS

GRANT APPLICATION RECEIPT DATES

National Institutes of Health
April 1, August 1, December 1, 2001 (SBIR and STTR)

Centers for Disease Control and Prevention
August 1 and December 1, 2001 (SBIR)

Food and Drug Administration
April 1, August 1, December 1, 2001 (SBIR)

Omnibus Solicitation of the
National Institutes of Health,
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SMALL BUSINESS INNOVATION RESEARCH (SBIR)

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U.S. Department of Health and Human Services

OMNIBUS SOLICITATION OF THE PUBLIC HEALTH SERVICE FOR SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND SMALL BUSINESS TECHNOLOGY TRANSFER RESEARCH (STTR) GRANT APPLICATIONS

IMPORTANT INFORMATION AND REMINDERS IN THIS SOLICITATION

- **CHANGE IN SBIR/STTR PHASE I AND PHASE II GRANT APPLICATION FORMS.** In late spring of calendar year 2001, pending approval from the Office of Management and Budget, NIH intends to use the revised Public Health Service Grant Application (PHS 398) for SBIR and STTR (Phase I and Phase II) applications. NIH is preparing the revised PHS 398 application for OMB approval. This endeavor is in concert with steps that NIH is taking toward streamlining the grant application procedures. The applications are used to request Federal assistance for research and research-related training. These forms are used by the following PHS agencies: National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substance and Disease Registry (ATSDR), and The Indian Health Service (IHS).

- ***Submissions for April 1, 2001 receipt date***. Applicants planning to submit a Phase I SBIR or Phase I STTR application on or before the April receipt date should use the SBIR Application Form (PHS 6246-1) or the STTR Application Form (PHS 6246-3). See Appendix A for instructions on completion and submission of these forms.

- ***Submissions after April 1, 2001 receipt date***. Applicants planning to submit an SBIR or STTR Phase I or Phase II grant application AFTER April receipt dates should check the NIH Small Business Funding Opportunities website http://grants.nih.gov/grants/funding/sbir.htm **for more specific details and instructions**.

- **CHANGE IN NUMBER OF COPIES.** Submit the ***original plus five*** exact, single-sided photocopies of each application.

- **BIOGRAPHICAL SKETCH PAGES.** Biographical sketch pages, limited to 3 pages per person, if necessary, are *excluded* from the 25-page limitation.

- **RESEARCH PLAN.** Sections A-D are limited to a total of 15 pages, including all tables and diagrams.

- **REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS.** Beginning on October 1, 2000, the NIH will require education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. Information about this policy may be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Frequently Asked Questions (http://grants.nih.gov/grants/policy/hs_educ_faq.htm) regarding this policy are also included in this Guide Announcement.

- **PHASE I BUDGET REQUEST THAT EXCEED 6 MONTHS.** Phase I SBIR/STTR Applicants requesting a budget period of more than 1 year (Requests That Exceed the 6-month Guidelines) must prepare applications according to the following instructions http://grants.nih.gov/grants/funding/sbir.htm#phase1.

- **SBIR/STTR SOLICITATION AVAILABILITY.** The SBIR/STTR Phase I Grant Solicitation *will only be available via electronic means*. *Printed copies of the Solicitation will not be distributed*. Potential applicants are encouraged to check the SBIR/STTR homepage frequently for updates on the program. Any updates or corrections to the solicitation will be posted there.

- **SBIR/STTR SOLICITATION FORMAT.** In an effort to prepare a more succinct and readable document, NIH has changed the format of the SBIR/STTR Phase I Solicitation in order to describe the research or R&D areas of interest for which applications are being solicited while leaving sufficient flexibility in order to obtain the greatest degree of creativity and innovation consistent with the overall objectives of the SBIR/STTR Programs.

REMINDERS** **REMINDERS**** **REMINDERS**** **REMINDERS**** **REMINDERS****

- **PHASE I PAGE LIMITATIONS.** SBIR/STTR Phase I applications may not exceed 25 single-spaced standard size (8 ½" x 11") pages, ***excluding*** Cover letters; One-page "Introduction" required when submitting a revised (amended) application; Biographical Sketch pages- a change from previous years- (limited to three pages per person, *if necessary*); Letters of commitment from collaborators and consultants; "Checklist" (Form Page 5);"Personal Data on Principal Investigator" Form Page; and, if applicable, Page(s) furnishing information required under "Prior SBIR/STTR Phase II Awards. The 25-page limit includes all other Form Pages and “continuation" pages suggested by the instructions.

- **TYPE SIZE SPECIFICATIONS.** The height of the letters must not be smaller than 10 point; type density must be no more than 15 characters per inch (cpi); there must be no more than 6 lines of type within a vertical inch. The type size used throughout the application must conform to ALL of these requirements. APPLICATIONS NOT MEETING THESE REQUIREMENTS WILL BE RETURNED WITHOUT REVIEW.

- **SINGLE OMNIBUS SOLICITATION FOR GRANT APPLICATIONS AND COINCIDENT RECEIPT DATES FOR SBIR/STTR GRANT APPLICATIONS.** Since the similarities between the NIH SBIR and STTR Grant Solicitations, both in research topics that may be of interest to small businesses and in application instructions, a single Omnibus Solicitation of the NIH, CDC, and FDA for SBIR/STTR Grant Applications has been issued for CY 2001 for coincident grant application receipt dates.

- **SPECIAL ANNOUNCEMENTS (Program Announcements/Requests for Applications) FOR SMALL BUSINESS RESEARCH OPPORTUNITIES.** Subscribe to the weekly content notifications via email using the NIH Guide Table of Contents Notification LISTSERV service (http://grants.nih.gov/grants/guide/listserv.htm.)

I. GENERAL PROGRAM DESCRIPTION

The Small Business Innovation Research (SBIR) program was established by the Small Business Research and Development Enhancement Act of 1992. Under this program, agencies of the Public Health Service (PHS), Department of Health and Human Services (HHS), and certain other Federal agencies are required to reserve 2.5% of their current fiscal year extramural budgets for small companies to conduct research or research and development (R/R&D).

The Small Business Technology Transfer (STTR) program, currently in five Federal agencies, was established by the Small Business Technology Transfer Act of 1992 (Public Law 102-564, Title II). Under this program, 0.15% of a Federal agency's extramural R/R&D effort is reserved for awards to small business concerns and their non-profit research institution partners for cooperative research and development efforts.

The objectives of the SBIR Program include stimulating technological innovation in the private sector, strengthening the role of small business in meeting Federal R/R&D needs, increasing private sector commercialization of innovations developed through Federal SBIR R&D, increasing small business participation in Federal R/R&D, and fostering and encouraging participation by socially and economically disadvantaged small business concerns and women-owned business concerns in the SBIR program.

The STTR program further expands the goals through cooperative research and development carried out between small business concerns and research institutions.

The National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA) invite eligible small business concerns to submit Phase I applications for the Calendar Year (CY) 2001 Small Business Innovation Research (SBIR) program and, applicable to NIH only, for the CY 2001 Small Business Technology Transfer (STTR) program.

Beginning in CY 2000, NIH issued a single Omnibus Solicitation of the NIH, CDC, and FDA for SBIR/STTR Grant Applications. Accordingly, a single Omnibus Solicitation of the NIH, CDC, and FDA for SBIR/STTR Grant Applications will be issued for CY 2001 grant application receipt dates.

NOTE: The CDC and FDA participate ONLY in the SBIR program.

This single SBIR/STTR solicitation (PHS 2001-2) provides information about each program. The significant difference between the SBIR and STTR programs is that the STTR requires the small business concern to have a formal collaboration with researchers at universities and other non-profit research institutions and play a significant intellectual role in the conduct of each STTR project. Also, unlike the SBIR Program, there is no stipulation under the STTR program that the Principal Investigator (PI) must have his/her primary employment with the small business concern. Therefore, the PI on an STTR may be from the small business concern or the research institution *as long as s/he has a formal appointment with or commitment to the applicant small business concern, which is characterized by an official relationship between the small business concern and that individual*.

A. SBIR/STTR PROGRAMS: THREE PHASES

PHASE I: Feasibility
$100,000
6 Months (SBIR)
1 Year (STTR)

The objective of Phase I is to establish the technical/scientific merit and feasibility of the proposed R/R&D efforts and to determine the quality of performance of the small business grantee organization prior to providing further Federal support in Phase II. *Preliminary data are not required*. SBIR Phase I awards normally may not exceed $100,000 total costs (direct costs, indirect costs, and negotiated fixed fee) for a period normally not to exceed 6 months. STTR Phase I awards normally may not exceed $100,000 total costs for a period of 1 year. For SBIR projects, the total amount of all contractual costs and consultant fees normally may not exceed 33% of the total costs requested. However, these award levels for time and amount are statutory guidelines, not ceilings. Therefore, applicants are encouraged to propose a budget and project period that is appropriate for completion of the research

project. Deviations from the guidelines are acceptable, *but must be well justified*. ***Applicants are encouraged to discuss budgetary deviations with NIH program staff prior to submission of the application.***

SBIR Phase I applications should be prepared using PHS 6246-1 forms and in accordance with SBIR instructions in Section XI. STTR Phase I applications should be prepared using PHS 6246-3 forms and in accordance with STTR instructions in Section XI. Evaluation and selection criteria are described in Section VI.

A Phase I Final Report is required for the completion of a Phase I SBIR/STTR project. All Phase I Final Reports should be prepared in accordance with the instructions in Section VII.

PHASE II: Full R/R&D Effort
~ $750,000 (SBIR)
~ $500,000 (STTR)
~ 2 Years

The objective of Phase II is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I, scientific and technical merit, and commercial potential of the Phase II application. SBIR Phase II awards normally may not exceed $750,000 in total costs (direct costs, indirect costs, and negotiated fixed fee) for a period normally not to exceed 2 years. STTR Phase II awards normally may not exceed $500,000 total costs (direct costs, indirect costs, and negotiated fixed fee) for a period normally not to exceed 2 years. However, these award levels for time and amount are statutory guidelines, not ceilings. Therefore, applicants are encouraged to propose a budget and project period that is appropriate for completion of the research project. Deviations from the guidelines are acceptable, *but must be well justified*. ***Applicants are encouraged to discuss budgetary deviations with NIH program staff prior to submission of the application.***

Only Phase I grantees are eligible to obtain Phase II funding, and only one Phase II award may be made for a single SBIR/STTR project. Phase II applications may be submitted either before or after expiration of the Phase I budget period, except for those applicants electing to submit Phase I and Phase II applications concurrently under the Fast-Track procedures (described in Section VI, item G).

Also, under special circumstances, requests for supplemental funds to existing Phase I grants or requests for an extension of the period of support with funds, may be considered. (*The awarding of supplemental funds applies to NIH ONLY, as CDC and FDA do not make awards greater than the stated guidelines.*)

PHASE III: Commercialization
No SBIR/STTR Funds

The objective of Phase III, where appropriate, is for the small business concern to pursue with non-SBIR/STTR funds (either Federal or non-Federal) the commercialization objectives resulting from the results of the research or R&D funded in Phases I and II. In some Federal agencies, Phase III may involve follow-on, non-SBIR/STTR funded R&D, or production contracts for products or processes intended for use by the U.S. Government.

B. FAST-TRACK APPLICATIONS

Fast Track Applications: PHASE I + II
Parallel review option
Phase I and Phase II submitted together
Product Development Plan

The NIH Fast-Track mechanism expedites the decision and award of SBIR and STTR Phase II funding for scientifically meritorious applications that have a high potential for commercialization. Fast Track incorporates a parallel review option, in which both Phase I and Phase II grant applications are submitted and reviewed together. As with other Phase I applications, preliminary data are not required. However, the Phase I portion of a Fast Track must specify clear, measurable goals (milestones) that should be achieved prior to initiating Phase II work. In addition, a Fast Track application must present a Product Development Plan that addresses specific points. Instructions on the preparation of a Fast Track application may be found in Section VI. G.

C. PURPOSE OF SOLICITATION

The purpose of this Solicitation is to invite Phase I grant applications from domestic small business concerns that have the technological expertise to contribute to the R&D mission(s) of the NIH, CDC, and FDA awarding components identified in the solicitation, and to provide to those applicants choosing the Fast-Track review option the opportunity to submit Phase II grant applications concurrently with Phase I

applications. *The CDC and FDA do not participate in the STTR program*.

This solicitation outlines the objectives of the agencies' SBIR/STTR grants program, the eligibility requirements for those small business concerns wishing to participate, and the application and review processes.

The research topics shown in the solicitation represent program areas that may be of interest to applicant small business concerns in the development of projects that have the potential for commercialization. Small business concerns are encouraged to submit SBIR/STTR grant applications in these areas.

NOTE: SBIR/STTR grant applications will be accepted and considered in any area within the mission of the awarding components identified in this solicitation.

Applicants are strongly encouraged to query program administrators periodically via email to learn of new or emerging scientific interests of the NIH, CDC, and FDA awarding components.

Additional information on each of the awarding components and their research interests is available electronically on the home pages shown throughout the "Research Topics" section of the solicitation.

D. SBIR/STTR PROGRAM ELIGIBILITY

Organizational Criteria

Each organization submitting a grant application under the SBIR/STTR program must qualify as a small business concern in accordance with the definition given in Section III. In determining whether an applicant is a small business concern, an assessment will be made of several factors, including whether or not it is independently owned and operated and whether or not it is an affiliate of a larger organization whose employees, when added to those of the applicant organization, exceed 500. In conducting this assessment, all appropriate factors will be considered, including common ownership, common management, and contractual relationships.

In accordance with Title 13 Code of Federal Regulations (CFR) Part 121.3, affiliation exists when either directly or indirectly "(i).one concern controls or has the power to control the other, or (ii) a third party or parties controls or has the power to control both." One of the circumstances that would lead to a finding that an organization is controlling or has the power to control another organization involves sharing common office space and/or employees and/or other facilities (e.g., laboratory space). 13 CFR 121.3 also states that control or the power to control exists when "key employees of one concern organize a new concern ... and serve as its officers, directors, principal stockholders, and/or key employees, and one concern is furnishing or will furnish the other concern with subcontracts, financial or technical assistance, and/or other facilities, whether for a fee or otherwise."

Where there is indication of sharing of common employees, a determination will be made on a case-by-case basis of whether such sharing constitutes control or the power to control.

All SBIR/STTR grant applications will be examined with the above considerations in mind. If it appears that an applicant organization does not meet eligibility requirements, the PHS will request a size determination of the organization from the cognizant Small Business Administration (SBA) regional office. Under these circumstances in which eligibility is unclear, no SBIR or STTR award will be made until a determination is provided by the SBA.

SBIR/STTR Eligibility Checkpoint

- ☑ **For- profit U.S. business firm.**
- ☑ **At least 51% U.S.- owned and independently operated.**
- ☑ **Small Business located in the U.S.**
- ☑ **Principal Investigator's primary employment with small business during project (SBIR only).**
- ☑ **500 or fewer employees.**

Performance of Research and Analytical Work by the Applicant Organization

SBIR

In Phase I, normally, a minimum of two-thirds or 67% of the research or analytical effort must be carried out by the small business concern. Therefore, consultant fees and contracts to third parties for portions of the scientific/technical

effort generally may not exceed 33% of the total budget, including direct costs, indirect costs, and fixed fee. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of direct and indirect costs attributable to each party, UNLESS OTHERWISE DESCRIBED AND JUSTIFIED IN THE "CONTRACTUAL ARRANGEMENTS" PORTION OF THE "RESEARCH PLAN" SECTION OF THE APPLICATION.

In Phase II, normally, a minimum of one-half or 50% of the research or analytical effort must be carried out by the small business concern. Therefore, consultant fees and contracts to third parties for portions of the scientific/technical effort generally may not exceed 50% of the total budget, including direct costs, indirect costs, and fixed fee. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of direct and indirect costs attributable to each party, UNLESS OTHERWISE DESCRIBED AND JUSTIFIED IN THE "CONTRACTUAL ARRANGEMENTS" PORTION OF THE "RESEARCH PLAN" SECTION OF THE APPLICATION.

The research and analytical work performed by the grantee organization is to be conducted in research space occupied by, available to, and under the control of the SBIR/STTR grantee for the conduct of its portion of the proposed project. However, when required by the project activity, access to special facilities or equipment in another organization is permitted, as in cases where the SBIR/STTR awardee has entered into a sub-contractual agreement with another institution for a specific, limited portion of the research project.

Whenever a proposed SBIR/STTR project is to be conducted in facilities other than those of the applicant organization, and if the application has the likelihood for funding, the awarding component will request that the small business concern provide a letter from the organization stating that leasing/rental arrangements have been negotiated for appropriate research space (i.e., space that will be available to and under the control of the SBIR/STTR grantee organization). This letter, to be signed by an authorized official of the organization whose facilities are to be used for the SBIR/STTR project, must certify that the small business concern will have unlimited access to and control over the research space. In addition, the letter must include a description of the facilities and, if appropriate, equipment that will be leased/rented to the grantee organization.

STTR

In Phase I and Phase II, at least 40% of the work must be performed by the small business concern and at least 30% of the work must be performed by the Research Institution. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of direct and indirect costs attributable to each party UNLESS OTHERWISE DESCRIBED AND JUSTIFIED IN THE "CONTRACTUAL ARRANGEMENTS" PORTION OF THE "RESEARCH PLAN" SECTION OF THE APPLICATION.

Performance Site Criteria

For both SBIR/STTR Phase I and Phase II, the research or R&D project activity must be performed in its entirety in the United States (see Section III, Definitions). In those rare circumstances that necessitate the use of foreign sites (e.g., patient populations) because of the study design, investigators must thoroughly justify the use of these sites in the application. Similarly, in those rare circumstances that necessitate the purchase of materials from other countries, investigators must thoroughly justify the request. These rare situations will be considered on a case-by-case basis. While the SBIR/STTR research or R&D project activity must be performed in its entirety in the United States, other work outside of the United States, which is necessary to the overall completion of the project, could be supported by non-SBIR/STTR funds.

Principal Investigator Criteria

SBIR

The primary employment of the Principal Investigator must be with the small business concern *at the time of award and during the conduct of the proposed project.* Primary employment means that more than one half of the Principal Investigator's time is spent in the employ of the small business concern. Primary employment with a small business concern precludes full-time employment at another organization.

As defined in 42 CFR 52, the Principal Investigator is the "single individual designated by the grantee in the grant application ... who is responsible for the scientific and technical direction of the project." When the proposed Principal Investigator clearly does not have sufficient qualifications to assume this role, the application is not likely to receive a favorable evaluation (see Section VII, Method of Selection and Evaluation Criteria).

If the application has the likelihood for funding, the awarding component will require documentation to verify the eligibility of the Principal Investigator. This will be necessary when, at the time of submission of the application, the Principal Investigator (1) is a less-than-full-time employee of the small business concern; (2) is concurrently employed by another organization; or (3) gives the appearance of being concurrently employed by another organization, whether for a paid or unpaid position.

That is to say, if the Principal Investigator is employed or appears to be employed by an organization other than the applicant organization in a capacity such as Research Fellow, Consultant, Adjunct Professor, Clinical Professor, Clinical Research Professor, or Associate, a letter must be provided by each employing organization confirming that, if an SBIR grant is awarded to the applicant small business concern, the Principal Investigator is or will become a less-than-half-time employee of such organization and will remain so for the duration of the SBIR project. If the Principal Investigator is employed by a university, such a letter must be provided by the Dean's office or equivalent; for other organizations, the letter must be signed by a corporate official.

This requirement applies also to those individuals engaged currently as the Principal Investigator on an active SBIR project. All current employment and all other appointments of the Principal Investigator must be identified in his or her "Biographical Sketch" required as part of the application. Be certain that correct beginning and ending dates are indicated for each employment record listed.

STTR

The Principal Investigator must have a formal appointment with or commitment to the applicant small business concern, which is characterized by an official relationship between the small business concern and that individual. Such a relationship does not necessarily involve a salary or other form of remuneration. In all cases, however, the Principal Investigator's official relationship with the grantee must entail sufficient opportunity for the Principal Investigator to carry out his or her responsibilities for the overall scientific and technical direction of the project. Documentation describing the official relationship of the Principal Investigator with the applicant small business concern should NOT be submitted with the grant application, but a copy must be furnished upon the request of the NIH awarding component.

Note: Signatures on the face page and the Research Institution budget page certify that the Principal Investigator has a formal relationship with/commitment to the small business concern.

Following are examples of situations describing the official relationship of the Principal Investigator with the applicant small business organization:

- A Principal Investigator with a full-time, university appointment may also have appointments (with or without salary) and still appropriately consider his or her commitment to the university to be "full-time," consistent with the personnel policies and procedures of the university applied on a routine basis. The Principal Investigator's commitment to the university and other organizations (including the applicant small business concern) cannot exceed 100% of his or her total professional effort.

- A Principal Investigator with a full-time, 12-month appointment with a small business concern would be considered to have a commitment to the applicant organization of 100% of his or her total professional effort.

- A Principal Investigator who has a part-time appointment with a small business concern and has concurrent commitments or appointments with organizations in addition to the small business concern would deem each commitment as a portion of 100% of his or her total professional effort.

As responsible stewards of funds, the NIH is concerned that the Principal Investigator has the time available to carry out the proposed STTR

research activities. Therefore, the Principal Investigator should take care to assure peer reviewers and NIH staff that the time proposed for a particular project is reasonable and that he or she has sufficient time (minimum 10% effort) available from among his or her total professional commitments to devote to this project.

II. AGENCY CONTACT FOR INFORMATION

The SBIR/STTR Phase I Grant Solicitation will ***only be available via electronic means.*** Printed copies of the Solicitation will not be distributed. The SBIR/STTR Phase I Grant Solicitation and the Phase II Grant Application package, both text and forms, are available electronically on the NIH's "Small Business Funding Opportunities" home page at http://grants.nih.gov/grants/funding/sbir.htm.

Program Officials/Agency Contact Information

Applicants are strongly encouraged to contact NIH program staff prior to submitting an SBIR/STTR grant application for information regarding research topics. The names, addresses, and communication numbers of other contacts as well as Internet websites for each PHS awarding component are included in Section X, Program Descriptions/Research

Topics. More detailed information on each of the NIH awarding components, as well as the CDC and FDA, and their research interests are available electronically on the home pages cited in the table and in Section X. For administrative and business management questions that are not answered in this solicitation, a grants management contact is identified.

Questions of a general nature about the NIH SBIR/STTR program should be directed to:

Ms. Jo Anne Goodnight
NIH SBIR/STTR Program Coordinator
6701 Rockledge Drive
Rockledge II, Room 6186
Bethesda, MD 20892-7911
Phone: 301-435-2688 Fax: 301-480-0146
Email: jg128w@nih.gov

or

PHS SBIR/STTR Solicitation Office
13687 Baltimore Avenue
Laurel, MD 20707-5096
Phone: (301) 206-9385
Fax: (301) 206-9722
E-mail: sbirsttr@peacetech.com

The following table includes points of contact information for each PHS awarding component.

AWARDING COMPONENT/AGENCY CONTACT INFORMATION		
AWARDING COMPONENT	**PROGRAM CONTACT**	**GRANTS MGMT. CONTACT**
National Institute on Aging http://www.nih.gov/nia	Dr. Miriam F. Kelty Phone: 301-496-9322 Fax: 301-402-2945 Email: mk46u@nih.gov	Ms. Linda Whipp Phone: 301-496-1472 Fax: 301-402-3672 Email: lw17m@nih.gov
National Institute on Alcohol Abuse and Alcoholism http://www.niaaa.nih.gov	Dr. Michael Eckardt Phone: 301-443-6107 Fax: 301-443-6077 Email: me25t@nih.gov	Ms. Linda Hilley Phone: 301-443-4704 Fax: 301-443-3891 Email: lh67b@nih.gov
National Institute of Allergy and Infectious Diseases http://www.niaid.nih.gov	Dr. Gregory Milman Phone: 301-496-8666 Fax: 301-402-0369 Email: gm16s@nih.gov	Ms. Mary Kirker Phone: 301-496-7231 Fax: 301-480-3780 Email: mk35h@nih.gov

AWARDING COMPONENT/AGENCY CONTACT INFORMATION		
AWARDING COMPONENT	**PROGRAM CONTACT**	**GRANTS MGMT. CONTACT**
National Institute of Arthritis and Musculoskeletal and Skin Diseases http://www.nih.gov/niams	Dr. Steven J. Hausman Phone: 301-594-2463 Fax: 301-480-4543 Email: sh41g@nih.gov	Ms. Florence Turska Phone: 301-594-3507 Fax: 301-480-5450 Email: ft7p@nih.gov
National Cancer Institute http://www.nci.nih.gov	Ms. Kay Etzler Phone: 301-496-1550 Fax: 301-496-7807 Email: etzlerk@mail.nih.gov	Ms. Kathleen Shino Phone: 301-846-1016 Fax: 301-846-1198 Email: ks48e@nih.gov
National Institute of Child Health and Human Development http://www.nichd.nih.gov	Dr. Louis A. Quatrano Phone: 301-402-2242 Fax: 301-402-0832 Email: lq2n@nih.gov	Ms. Diane Watson Phone: 301-435-6975 Fax: 301-402-0915 Email: dw40j@nih.go v
National Institute on Drug Abuse http://www.nida.nih.gov	Dr. Cathrine Sasek Phone: 301-443-1056 Fax: 301-443-6277 Email: csasek@nih.gov.	Mr. Gary Fleming Phone: 301-443-6710 Fax: 301-594-6847 Email: gf6s@nih.gov
National Institute on Deafness and Other Communication Disorders http://www.nih.gov/nidcd	Dr. Lynn E. Luethke Phone: 301-402-3458 Fax: 301-402-6251 Email: lh99s@nih.gov	Ms. Sharon Hunt Phone: 301-402-0909 Fax: 301-402-1758 Email: sh79f@nih.gov
National Institute of Dental and Craniofacial Research http://www.nidcr.gov	Dr. Eleni Kousvelari Phone: 301-594-2427 Fax: 301-480-8318 Email: Eleni.Kousvelari@nih.gov	Mr. Martin Rubinstein Phone: 301-594-4800 Fax: 301-480-8301 Email: mr49c@nih.gov
National Institute of Diabetes and Digestive and Kidney Diseases http://www.niddk.nih.gov	Dr. Judith Podskalny Phone: 301-594-8876 Fax: 301-480-8300 Email: jp53s@nih.gov	Mr. George Tucker Phone: 301-594-8853 Fax: 301-480-3504 Email: gt35v@nih.gov
National Institute of Environmental Health Sciences http://www.niehs.nih.gov	Dr. Jerrold Heindel Phone: 919-541-0781 Fax: 919-541-5064 Email: jh190f@nih.gov	Ms. Carolyn Winters Phone: 919-541-7823 Fax: 919-541-2860 Email: cw47d@nih.gov
National Eye Institute http://www.nei.nih.gov	Dr. Ralph Helmsen Phone: 301-496-5301 Fax: 301-402-0528 Email: rh27v@nih.gov	Mr. William Darby Phone: 301-496-5884 Fax: 301-496-9997 Email: wwd@nei.nih.gov
National Institute of General Medical Sciences http://www.nih.gov/nigms	Dr. Peter Preusch Phone: 301-594-1832 Fax: 301-480-2802 Email: pp27g@nih.gov	Ms. Linda Roberts Phone: 301-594-5141 Fax: 301-480-1969 Email: lr24v@nih.gov
National Heart, Lung, and Blood Institute http://www.nhlbi.nih.gov	Dr. John T. Watson Phone: 301-435-0513 Fax: 301-480-1336 Email: jw53f@nih.gov	Mr. Ed Donohue Phone: 301-435-0144 Fax: 301-480-3310 Email: ed25b@nih.gov

AWARDING COMPONENT/AGENCY CONTACT INFORMATION		
AWARDING COMPONENT	**PROGRAM CONTACT**	**GRANTS MGMT. CONTACT**
National Human Genome Research Institute http://www.nhgri.nih.gov	Dr. Bettie J. Graham Phone: 301-496-7531 Fax: 301-480-2770 Email: bg30t@nih.gov	Ms. Jean Cahill Phone: 301-402-0733 Fax: 301-402-1951 Email: jc166o@nih.gov
National Institute of Mental Health http://www.nimh.nih.gov	Dr. Michael F. Huerta Phone: 301-443-5625 Fax: 301-443-1731 Email: mh38f@nih.gov	Mr. Michael Loewe Phone: 301-435-7008 Fax: 301-402-0915 Email: ml70m@nih.gov
National Institute of Neurological Disorders and Stroke http://www.ninds.nih.gov	Dr. Thomas Miller Phone: 301-496-1779 Fax: 301-402-1501 Email: tm208y@nih.gov	Ms. Kathleen Howe Phone: 301-496-9231 Fax: 301-402-0219 Email: kh52x@nih.gov
National Institute of Nursing Research http://www.nih.gov/ninr	Dr. Hilary Sigmon Phone: 301-594-5970 Fax: 301-480-8260 Email: hs38k@nih.gov	Ms. Cindy McDermott Phone: 301-594-6869 Fax: 301-480-8260 Email: cm253t@nih.gov
National Center for Research Resources http://www.ncrr.nih.gov	Dr. Louise E. Ramm Phone: 301-435-0879 Fax: 301-480-3658 Email: lr34m@nih.gov	Mr. Bryan Clark Phone: 301-435-0844 Fax: 301-480-3777 Email: ClarkB@ncrr.nih.gov
National Center for Complementary and Alternative Medicine http://nccam.nih.gov	Dr. Richard Nahin Phone: 301-496-4792 Fax: 301-402-4741 Email: rn8p@nih.gov	Ms. Suzanne White Phone: 301-435-0171 Fax: 301-480-3310 Email: sw52h@nih.gov
National Library of Medicine http://www.nlm.nih.gov	Mr. Milton Corn Phone: 301-496-4621 Fax: 301-402-0421 Email: pc49n@nih.gov	Mr. John Seachrist Phone: 301-496-4221 Fax: 301-402-0421 Email: js132f@nih.gov
Centers for Disease Control and Prevention (CDC) http://www.cdc.gov	Ms. Nina Waters Phone: 770-488-2805 Fax: 770-488-2847 Email: jvw0@cdc.gov	Ms. Joanne Wojcik Phone: 770-488-2717 Fax: 770-488-2777 Email: jcw6@cdc.gov
Food and Drug Administration (FDA) http://www.fda.gov	Ms. Rosemary Springer Phone: 301-827-7182 Fax: 301-827-7106 Email: rspringe@oc.fda.gov	Ms. Olia Hopkins Phone: 301-827-7150 Fax: 301-827-7106 Email:ohopkins@oc.fda.gov

III. DEFINITIONS

Commercialization. The process of developing markets and producing and delivering products for sale (whether by the originating party or by others); as used here, commercialization includes both government and private sector markets.

Collaborator. An individual involved with the Principal Investigator in the scientific development or execution of the project. These individuals would typically devote a specific percent of effort to the project and would be identified as key personnel. The collaborator may be employed by, or affiliated with, either the grantee organization or an organization participating in the project under a consortium or contractual agreement.

Consortium or Contractual Agreement. An agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. In this arrangement, the grantee contracts for the performance of a substantial and/or significant portion of the activities to be conducted under the grant. These agreements typically involve a specific percent of effort from the consortium organization's Principal Investigator and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including indirect costs.

Consultant. An individual hired to give professional advice or services for a fee, normally not as an employee of the hiring party. Consultants may also include firms that provide paid professional advice or services.

Contract. An award instrument establishing a binding legal procurement relationship between a funding agency and the recipient, obligating the latter to furnish an end product or service and binding the agency to provide payment therefore.

Cooperative Agreement. A financial assistance mechanism to be used in lieu of a grant when substantial Federal programmatic involvement with the recipient during performance is anticipated by the PHS awarding component.

Essentially Equivalent Work. This term is meant to identify "scientific overlap," which occurs when (1) substantially the same research is proposed for funding in more than one proposal (contract proposal or grant application) submitted to the same Federal agency; OR (2) substantially the same research is submitted to two or more different Federal agencies for review and funding consideration; OR (3) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more proposals or awards, regardless of the funding source.

Feasibility. The extent to which a study or project may be done practically and successfully.

Grant. A financial assistance mechanism whereby money and/or direct assistance is provided to carry out approved activities.

Innovation. Something new or improved, including research for (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For the purposes of PHS programs, an example of "innovation" would be new medical or biological products, for improved value, efficiency, or costs.

Key Personnel Engaged on Project. This term is meant to identify those individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested.

Principal Investigator. The one individual designated by the applicant organization to direct the project or program to be supported by the grant. The Principal Investigator is responsible and accountable for the proper conduct of the project or program.

Program Income. Gross income earned by a grant recipient during the budget period of the grant as a result of activities supported by the grant award. The *NIH Grants Policy Statement* (http://grants.nih.gov/grants/policy/nihgps) contains a detailed explanation of program income, ways in which it may be generated and accounted for, and the various options for its use and disposition.

Examples of program income include:

- Patent or copyright royalties.
- Fees earned from services performed under the grant, such as those resulting from laboratory drug testing.
- Rental or usage fees, such as those earned from fees charged for use of computer equipment purchased with grant funds.
- Third-party patient reimbursement for hospital or other medical services, such as insurance payments for patients when such reimbursement occurs because of the grant-supported activity.
- Funds generated by the sale of products developed under the grant, which include but are not limited to drugs, assays, devices, instrumentation, software, laboratory techniques/methodologies, and testing/training devices or systems.

- Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals.

Generally, SBIR/STTR grantee organizations that earn program income may be authorized to have such income added to the grant account and used to further the objectives of the research project. Authorization must be requested from the Grants Management Officer of the appropriate PHS awarding component.

Prototype. A model of something to be further developed and includes designs, protocols, questionnaires, software, devices, etc.

Research Institution. A United States research organization that is:

- A nonprofit college or university OR
- A nonprofit research institution, including nonprofit medical and surgical hospitals. (A "nonprofit institution" is defined as an organization that is owned and operated exclusively for scientific or educational purposes, no part of the net earnings of which inures to the benefit of any private shareholder or individual.) OR
- A contractor-operated, federally funded research and development center, as identified by the National Science Foundation in accordance with the Government-wide Federal Acquisition Regulation issued in accordance with section 35(c)(1) of the Office of Federal Procurement Policy Act (or any successor legislation thereto).

(*Laboratories staffed by Federal employees do not meet the definition of "research institution" for purposes of the STTR program.*)

Research or Research and Development (R/R&D). Any activity that is:

- A systematic, intensive study directed toward greater knowledge or understanding of the subject studied.
- A systematic study directed specifically toward applying new knowledge to meet a recognized need.
- A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

Small Business Concern. A small business concern is one that, at the time of award of Phase I and Phase II, meets the following criteria:

1. Is independently owned and operated, is not dominant in the field of operation in which it is proposing, has its principal place of business located in the United States, and is organized for profit.
2. Is at least 51% owned, or in the case of a publicly owned business, at least 51% of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens.
3. Has, including its affiliates, *a number of employees not exceeding 500*, and meets the other regulatory requirements found in 13 CFR Part 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both.

Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR 121.3-2(a). The term "number of employees" is defined in 13 CFR 121.3-2(t).

Business concerns include, but are not limited to, any individual (sole proprietorship), partnership, corporation, joint venture, association, or cooperative. Further information may be obtained by contacting the Small Business Administration Size District Office at http://www.sba.gov/size/.

Socially and Economically Disadvantaged Individual. A member of any of the following groups:

1. Black Americans

2. Hispanic Americans
3. Native Americans
4. Asian-Pacific Americans
5. Subcontinent Asian Americans
6. Other groups designated from time to time by SBA to be socially disadvantaged
7. Any other individual found to be socially and economically disadvantaged by SBA pursuant to Section 8(a) of the Small Business Act, 15 U.S.C. 637(a)

Socially and Economically Disadvantaged Small Business Concern. A socially and economically disadvantaged small business concern:

1. Is one that is at least 51% owned by (a) an Indian tribe or a native Hawaiian organization, or (b) one or more socially and economically disadvantaged individuals; AND
2. Whose management and daily business operations are controlled by one or more socially and economically disadvantaged individuals.

Subcontract. Any agreement, other than one involving an employer-employee relationship, entered into by a Federal Government prime contractor calling for supplies or services required solely for the performance of the prime contract or another subcontract.

United States. The 50 states, territories and possessions of the U.S., Commonwealth of Puerto Rico, Trust Territory of the Pacific Islands, and District of Columbia.

Women-Owned Small Business Concern. A small business concern that is at least 51% owned by a woman or women who also control and operate it. "Control" in this context means exercising the power to make policy decisions. "Operate" in this context means being actively involved in the day-to-day management.

IV. GRANT APPLICATION PREPARATION INSTRUCTIONS AND REQUIREMENTS

REFER TO "SPECIFIC GRANT APPLICATION PREPARATION INSTRUCTIONS AND REQUIREMENTS" FOR MORE DETAILED INFORMATION IN THE PREAPRATION OF YOUR GRANT APLICATION.

In late spring of calendar year 2001, pending approval from the Office of Management and Budget, NIH intends to use the revised Public Health Service Grant Application (PHS 398) for SBIR and STTR (Phase I and Phase II) applications submitted to NIH, CDC and FDA.

This endeavor is in concert with steps that NIH is taking toward streamlining the grant application procedures. The PHS 398 application is used to request Federal assistance for research and research-related training. These forms are used by the following PHS agencies: National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substance and Disease Registry (ATSDR), and The Indian Health Service (IHS).

- Applicants planning to submit a Phase I SBIR or STTR application *prior to April* should use the *SBIR Application Form (PHS 6246-1)* or the *STTR Application Form (PHS 6246-3)*. These forms, as well as instructions for completion and submission, are available electronically at http://grants.nih.gov/grants/funding/sbirsttr1/index.htm.

- Applicants planning to submit an SBIR or STTR Phase I or Phase II grant application after April receipt dates should check the NIH Small Business Funding Opportunities website http://grants.nih.gov/grants/funding/sbir.htm for more specific details and instructions.

Potential applicants are *strongly encouraged to contact program staff (see Section X) for pre-application guidance and/or for more specific information* on the research topics described in this solicitation.

A. LIMITATIONS ON LENGTH OF APPLICATION

Observe the page number limitations or the application will be returned without review.

1. SBIR/STTR Phase I applications *may not exceed 25 single-spaced standard size (8 ½" x 11") pages, excluding cover letter,* one-page "Introduction" required when

submitting a revised (amended) application, Biographical Sketch (limited to 3 pages for each key person), letters of commitment from collaborators and consultants, "Checklist" (Form Page 5), "Personal Data on Principal Investigator" Form Page, and page(s) furnishing information required under "Prior SBIR/STTR Phase II Awards" (Section IV, item H), if applicable. The 25-page limit includes all other form pages and "continuation" pages suggested by these instructions or application form pages. Note: Sections A-D of the Research Plan are limited to a total of 15 pages.

2. Phase I appendices are not permitted and, if submitted, they will not be considered in the review of the application for scientific and technical merit.

B. TYPE SIZE

Type size specifications must be observed throughout the application or the application will be returned without review.

The application must be clear, readily legible, and conform to the following requirements:

1. The height of the letters must not be smaller than 10 point.
2. Type density must be no more than 15 characters per inch (cpi). For proportional spacing, the average for any representative section of text must not exceed 15 cpi.
3. There must be no more than 6 lines of type within a vertical inch.
4. Margins must be at least ½ inch wide.
5. Figures, charts, tables, figure legends, and footnotes may be smaller in size but MUST be readily legible.

Type requirements should be checked on the printed document using a standard device for measuring type size, rather than relying on the font selected for a particular word processing/ printer combination. *The type size used throughout the application must conform to ALL of these requirements - applications not meeting these requirements will be returned without review*.

C. FORM PAGE ENTITLED "PERSONAL DATA ON PRINCIPAL INVESTIGATOR"

As part of the design and implementation of Electronic Research Administration, the Public Health Service (PHS) is assessing measures for protecting private information, including the Social Security Number (SSN). Although the provision of the SSN is voluntary, it is critically important to the PHS for the accurate identification, referral, and review of applications and for efficient management of PHS grant programs. To provide the PHS with the information it needs for this important task, the *SSN of the Principal Investigator should be provided at the top of the "Personal Data on Principal Investigator" form ONLY. The SSN should NOT be listed on the face page of the application, nor provided elsewhere in the application, for example, at the top of each application page*.

In accordance with the instructions for completing the "Personal Data on Principal Investigator" form, attach it to the signed original of the application after the Checklist. *Do not attach copies of this form to the duplicate copies of the application*.

Upon receipt of the application by the PHS, this form will be separated from the application. This *form will NOT be duplicated, and it will NOT be part of the review process*. Data will be confidential and will be maintained in the Privacy Act record system 09-25-0036, "Grants: IMPAC (Grant/Contract Information)." A partially completed Personal Data Form Page is acceptable; that is, the proposed Principal Investigator may elect to provide some items but not all.

D. MARKET RESEARCH

The PHS will not support any market research under the SBIR/STTR programs. Neither will it support studies of the literature that will lead to a new or expanded statement of work. Literature searches where the commercial product is a database are acceptable.

For purposes of the SBIR/STTR programs, "market research" is the systematic gathering, editing, recording, computing, and analyzing of data about problems relating to the sale and distribution of the subject of the research project. It includes various types of research, such as

the size of potential market and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, "market research" does not include activities under a research plan or protocol that require a survey of the public as part of the objective of the project to determine the impact of the subject of the research on the behavior of individuals.

E. PRIOR SBIR PHASE II AWARDS

A small business concern that submits an SBIR Phase I application and that has received more than 15 Phase II SBIR awards during the preceding five (5) fiscal years must document the extent to which it was able to secure Phase III funding to develop concepts resulting from previous Phase II SBIR awards. The following information must be submitted in the Phase I application regarding each such prior Phase II award: (1) name of awarding agency; (2) award number and date; (3) amount of award; (4) title of project; (5) source, date, and amount of Phase III funding agreement; and (6) commercialization status of each Phase II award shown in item 1 above.

F. ASSIGNMENT OF GRANT APPLICATIONS

The Center for Scientific Review (CSR) will assign appropriately completed applications to the Scientific Review Groups (commonly referred to as "SRGs" or "study sections") that will perform the scientific/ technical merit review. In addition, CSR will assign each application to the agency awarding component that is the potential funding component.

Cover Letters. When submitting an application, the small business concern applicant organization may include a cover letter to suggest an awarding component(s) to which it could be appropriately assigned for potential funding, to indicate a specific area of expertise that should be represented on the study section, and to indicate a direct conflict of interest.

Identify competitors who have direct conflicts of interest. When the scientific areas and the research proposed in a grant application are sufficiently relevant to the program responsibilities of two or more awarding components, CSR may assign the application to all such components. The component that has the most relevant program responsibility is designated as the primary assignee. The other components that have an interest in the application are designated as secondary assignees. If the application is eligible for funding and the primary assignee does not intend to make an award, the secondary assignees will be given the opportunity to do so. Although these suggestions will be taken into consideration, the final determination will be made by the agencies participating in this solicitation.

Cover Letters:

- **Request assignment(s) to potential awarding components.**
- **Indicate requisite study section expertise.**
- **Identify competitors who have direct conflicts of interest.**

V. SUBMISSION OF SBIR/STTR GRANT APPLICATIONS

The NIH's Center for Scientific Review (CSR) is the single receiving point for all NIH, CDC, and FDA SBIR/STTR grant applications.

A. RECEIPT DATES

NOTE: In CY 2001, SBIR and STTR applications have the same receipt dates.

Grant applications submitted under this SBIR/STTR Phase I Grant Solicitation must be received by the published receipt dates. *If the receipt date falls on a weekend, it will be extended to the following Monday; if the date falls on a holiday, it will be extended to the following workday*. An application received after the published receipt date may be acceptable if it carries a legible proof-of-mailing date assigned by the carrier and the proof-of-mailing date is not later than one week prior to the deadline date. The receipt date will be waived only in extenuating circumstances. To request a waiver, include an explanatory letter, addressed to the Division of Receipt and Referral, Center for Scientific Review, with the signed, completed application. No request for a waiver will be considered prior to receipt of the application, and there is no guarantee that the waiver will be granted.

Receipt of SBIR/STTR Phase II Applications (non-"Fast-Track")

Phase II applications may be *submitted on any of the three scheduled receipt dates identified below, either before or after expiration of the Phase I budget period*. However, *Phase II grant applications should be submitted no later than the first six receipt dates following expiration of the Phase I budget period*.

Applicant small business concerns are reminded that Phase II funding is based on the results of Phase I, demonstration of feasibility, scientific and technical merit, and commercial potential of the Phase II application. Applicants are cautioned that applications demonstrating insufficient results in Phase I may not receive a score in the peer review process (see Section VI, Method of Selection and Evaluation Criteria).

Receipt of Fast Track Applications

Fast Track applications may be submitted on any of the three scheduled receipt dates below. The face pages for both the Phase I and Phase II portions should be clearly marked "Fast Track", and copies of both portions should be assembled and submitted together.

SBIR AND STTR RECEIPT DATES PHASE I AND PHASE II	NATIONAL TECHNICAL MERIT REVIEW	ADVISORY COUNCIL BOARD REVIEW	ESTIMATED AWARD DATE
April 1, 2001	June/July	Sept/Oct	November
August 1, 2001	Oct/Nov	Jan/Feb	March
December 1, 2001 *	Feb/March	May/June	July

Applications to the Centers for Disease Control and Prevention may be submitted only on the August 1 and December 1 receipt dates.

CDC and FDA do not participate in the STTR program.

B. NUMBER OF COPIES

Original Plus 5 Copies

Submit the original and five exact, clear, single-sided photocopies of each application. The *original* must be signed by the Principal Investigator and a corporate official authorized to act for the applicant organization.

C. BINDINGS AND PACKAGING

Do not bind or staple the six sets together, but secure each with rubber bands or paper clips. *Do not include more than one set* of applications in each mailing envelope.

D. MAILING AND/OR DELIVERY ADDRESSES

Mail or deliver the complete, signed, and typewritten original and five signed, exact, clear, single-sided photocopies of the application in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive
Room 1040-MSC 7710
Bethesda, MD 20892-7710
Phone: (301) 435-0715

Change zip code to 20817 for express mail or courier service.

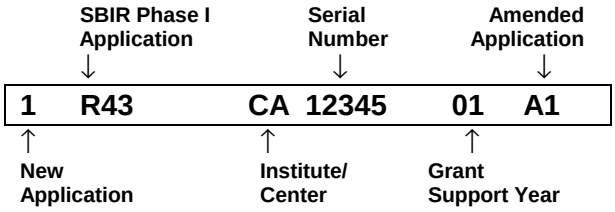
E. NOTIFICATION OF RECEIPT

Usually within six weeks after the receipt date, the CSR/NIH will send the Principal Investigator and the applicant organization a notification of receipt of the application. The mailer will indicate a grant application assignment number as well as the name, address, and telephone number of the Scientific Review Administrator

(SRA) of the Scientific Review Group (SRG) to which the application has been assigned. If this information is *not received within that time, contact*:

Division of Receipt and Referral
Center for Scientific Review, NIH
(301) 435-0715; Fax: (301) 480-1987

Sample Grant Application Assignment Number



F. INCOMPLETE APPLICATIONS

Do not submit an incomplete application. An application will be considered incomplete and will be returned if it is illegible, if it does not conform to the instructions, or if the material presented is insufficient to permit an adequate review.

G. SUPPLEMENTARY OR CORRECTIVE INFORMATION

Supplementary or corrective material pertinent to the review of an application may be submitted after the receipt date, but only if it is specifically solicited by or agreed to through prior discussion with the Scientific Review Administrator of the SRG. In no instance can the original Phase I application plus supplementary materials exceed the Phase I Research Plan page limitations. In addition, the submission of CD-ROM disks as demonstration materials for Phase I SBIR/STTR applications is forbidden.

VI. METHOD OF SELECTION AND EVALUATION CRITERIA

All Phase I and Phase II grant applications will be evaluated and judged on a competitive basis. Initially, applications will be screened for completeness and *those found to be incomplete in any way or programmatically unrelated to the agency's mission will be returned* without review to the applicant small business concern. Those passing the initial screening will be reviewed for technical and scientific merit. Each application will be judged on its own merit, according to the review criteria described below. The participating agencies are under no obligation to fund any specific application or make any specific number of awards in a given research topic area. Also, they may elect to fund several or none of the proposed projects within a given topic area.

A. REVIEW PROCESS

Grant applications are subjected to a peer review process involving two sequential steps that are required by law. The first step is performed by the Scientific Review Groups (SRGs), composed primarily of non-Federal scientists, physicians, and engineers (from academia and industry) selected for their expertise and stature in particular scientific fields. The second step is performed by the National Advisory Council or Board of the potential awarding component (Institute, Center, or other unit) to which the grant application is assigned.

SCIENTIFIC REVIEW GROUPS

The first task of the SRGs is to evaluate each SBIR/STTR application for scientific and technical merit and potential for commercialization, and to make an SRG recommendation for each application on the basis of this evaluation. While NIH uses a numerical range from 1.00 (most meritorious) to 5.00 (least meritorious), a streamlined procedure is used to determine those applications that the SRG considers to be in the “upper” or “lower half”. Applications in the “upper half” are discussed by the SRG and *generally* receive a score between 1.0 and 3.0, and applications in the “lower half” are not discussed and receive an “unscored” designation (i.e., those that would generally have received a score between 3.0 and 5.0). However, any review group member may identify an application that he or she believes should be discussed at the meeting and receive a numerical score. Under the currently employed streamlining procedures, a rating of 3.00 would be considered the median score for the cohort of applications that a scientific review group might review.

Individual reviewers mark scores to two significant figures, e.g., 1.2, and the individual

scores are averaged and then multiplied by 100 to yield a single overall score for each scored application, e.g., 153. Abstaining members and those not present during the discussion do not assign a numerical rating and are not counted in calculating the average of the individual ratings.

The second task of the SRGs is to make budget recommendations concerning time and dollar amounts that are appropriate for the work proposed. The SBIR/STTR Phase I review criteria are listed in item C below.

Regardless of the study section recommendation, all applicants receive a summary statement that includes a single rating/designation and the essentially unedited, verbatim critiques of two or more assigned reviewers.

NATIONAL ADVISORY COUNCIL OR BOARD

The second level of review is performed by the National Advisory Council or Board of the potential awarding component (Institute, Center, or other unit) to which the grant application is assigned. These groups, composed of scientists, physicians, and members of the public, are chosen for their expertise, interest, or activity in matters related to the awarding component's mission. In order for an application to be funded, it must be recommended by the Council or Board.

B. RELEASE OF GRANT APPLICATION REVIEW INFORMATION

Following evaluation of grant applications by the SRGs but prior to National Advisory Council or Board action, summary statements will be sent automatically to Principal Investigators.

Applicants normally receive their summary statement within four to six weeks following the study section meeting in which it was reviewed. A "summary statement" documents the evaluation of an application by the SRG and conveys the SRG's recommendations to the awarding component and its Council or Board. No one other than the Principal Investigator (and appropriate NIH staff) may receive the summary statement and evaluation rating.

After the review meeting occurs, applicants are encouraged to address inquiries about review to their Program Director, rather than to review staff. After receipt/review of the summary statement, applicants are encouraged to contact their Program Director for guidance and advice.

C. SBIR/STTR REVIEW CRITERIA

"Formulae" do not exist for calculating an individual reviewer's score on an application. In considering the scientific and technical merit of each application, the following criteria will be used:

1. ***Significance***

   - Does the proposed project have commercial potential to lead to a marketable product or process? Does this study address an important problem?
   - What may be the anticipated commercial and societal benefits of the proposed activity?
   - If the aims of the application are achieved, how will scientific knowledge be advanced?
   - Does the proposal lead to enabling technologies (e.g., instrumentation, software) for further discoveries?
   - Will the technology have a competitive advantage over existing/alternate technologies that can meet the market needs?

2. ***Approach***

   - Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project?
   - Is the proposed plan a sound approach for establishing technical and commercial feasibility?
   - Does the applicant acknowledge potential problem areas and consider alternative strategies?
   - Are the milestones and evaluation procedures appropriate?

3. ***Innovation***

   - Does the project challenge existing paradigms or employ novel technologies, approaches or methodologies?
   - Are the aims original and innovative?

4. ***Investigators***

   - Is the Principal Investigator capable of coordinating and managing the proposed SBIR/STTR?
   - Is the work proposed appropriate to the experience level of the Principal Investigator and other researchers, including consultants and sub-awardees (if any)?

5. ***Environment***

   - Is there sufficient access to resources (e.g., equipment, facilities)?
   - Does the scientific and technological environment in which the work will be done contribute to the probability of success?
   - Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?

In accordance with NIH policy, all applications will also be reviewed with respect to the following:

- The adequacy of plans to include genders, minorities, and their subgroups, and children, as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.
- The adequacy of the proposed protection for humans, animals, or the environment to the extent they may be adversely affected by the project proposed in the application.
- The appropriateness of the proposed budget and its duration in relation to the proposed research.

Phase II Applications

In addition to the above criteria, to what degree was progress toward the Phase I objectives met and feasibility demonstrated in providing a solid foundation for the proposed Phase II activity?

Phase I/Phase II Fast Track Applications

For Phase I/Phase II Fast Track applications, the following additional criteria will be applied:

- Does the Phase I application specify clear, appropriate measurable goals (milestones) that should be achieved prior to initiating Phase II?
- Did the applicant submit a concise Product Development Plan that adequately addresses the four areas described in Section VI, item G of this solicitation?
- To what extent was the applicant able to obtain letters of interest, additional funding commitments, and/or resources from the private sector or non-SBIR/STTR funding sources that would enhance the likelihood for commercialization?
- Does the project carry a high degree of commercial potential, as described in the Product Development Plan?

D. FUNDING DECISIONS

When making funding decisions, the awarding components take into consideration the following: (1) ratings resulting from the scientific and technical evaluation process; (2) areas of high program relevance; (3) program balance (that is, balance among areas of research); (4) available funds; and (5) the commercialization status where the small business concern has received more than 15 Phase II awards in the prior five (5) fiscal years, if applicable (see this application requirement under “Prior SBIR Phase II Awards” found in the “Introduction and Application Instructions” portion of the solicitation). The awarding component will notify the Principal Investigator and the applicant small business concern of the final disposition of the application.

Fast-Track Phase II applications that are recommended for approval may be funded following submission of the Phase I progress

report and other documents necessary for continuation. Phase II applications will be selected for funding based on the project's scientific and technical merit, the awarding component's assessment of the Phase I progress report and determination that the Phase I goals were achieved, an update and verification of the Product Development Plan and any commitment(s) for funds and/or resources from an investor or partner organization, as described below, the project's potential for meeting the mission of the awarding component and for commercial success, and the availability of funds.

E. REVISION AND RESUBMISSION OF GRANT APPLICATIONS

Grant applications that are not funded may be revised for resubmission at a future receipt date. However, applicant organizations may submit no more than two revised (amended) applications within a time period of two years from the receipt date of the initial, original application. The limit of two revisions allows applicant small business concerns and Principal Investigators sufficient time to consider new findings in the area of research and to take a fresh start at their research plans.

Resubmitted applications without substantive changes will not be accepted. The revised application MUST address the issues identified in the previous summary statement for the previous submission that was not fund. *Revised sections must be clearly marked (as described in the "Introduction and Application Instructions" portion of this solicitation).* Upon acceptance of a revised application by the CSR, the prior version will be withdrawn from further consideration by the awarding components. Acceptance of the revised application will generally mean that it will fall into a later review and award cycle. *Resubmission of an application that merely duplicates a previous application is not acceptable and the duplicate application will be returned without review*.

Amended (revised) Applications

For amended applications, in addition to the five review criteria described above, the following review criteria will be applied:

- Are the responses to comments from the previous Study Section adequate?
- Are the improvements in the revised application appropriate?

F. SUBMISSION OF SIMILAR GRANT APPLICATIONS BY THE APPLICANT ORGANIZATION

The submission of similar grant applications to the NIH by the same applicant small business concern is strongly discouraged. Principal Investigators are cautioned not to prepare multiple grant applications with essentially the same research focus, that is, a product or technology that, with non-substantive modifications, can be applied to a variety of purposes. In evaluating groupings of applications with a common scientific focus or objective (for example, implantation sensors/sensor materials, medical applications of lasers, immunology/immunoassays), SRGs are in a position to easily identify multiple grant applications from the same small business concern for essentially the same project. In these cases, the HHS will give funding consideration to only one application.

G. PHASE I/PHASE II FAST-TRACK REVIEW OPTION (Applicable to NIH Only)

The SBIR/STTR "Fast-Track" procedures described below are designed to expedite the decision and award of Phase II funding for scientifically meritorious applications for projects that have a high potential for commercialization. Fast-Track is a parallel review option available to those small business concerns (applicant organizations) whose applications satisfy additional criteria that enhance the probability of the project's commercial success. Applications that do not meet these criteria may be redirected for review through the standard review procedures described above.

Fast-Track offers two major advantages:

- Concurrent submission and peer review of both Phase I and Phase II projects.
- Minimal or no funding gap between Phase I and Phase II.

Fast-Track Phase II applications that are recommended for approval may be funded following submission of the Phase I progress report and other documents necessary for

continuation. Phase II applications will be selected for funding based on the project's scientific and technical merit, the awarding component's assessment of the Phase I progress report and determination that the Phase I goals were achieved, an update and verification of the Product Development Plan and any commitment(s) for funds and/or resources from an investor or partner organization, as described below, the project's potential for meeting the mission of the awarding component and for commercial success, and the availability of funds.

SBIR/STTR Fast-Track Application Instructions and Requirements

- Complete Phase I and Phase II applications (including the Face page, Abstract, Budget, Biographical Sketch and Bibliography, and Research Plan) must be submitted in accordance with specific Phase I and Phase II grant application instructions and requirements. Incomplete Fast Track Applications will be returned without review.

- Identify the application as Fast-Track, by typing the words "Fast-Track" in Item 2 on the Face Page of the Phase I application. Also, type "fast-track" in **Item 1b** on the face page of the Phase II application.

- Prepare and submit both a Phase I and Phase II SBIR/STTR application together for concurrent initial peer review and evaluation. SBIR and STTR Phase I application forms and instructions are available electronically at http://grants.nih.gov/grants/funding/sbirsttr1/11instructions.htm. SBIR Phase II application forms and instructions (http://grants.nih.gov/grants/funding/sbir2/intro.htm as well as STTR Phase II application forms and instructions http://grants.nih.gov/grants/funding/sttr2/intro.html are also available electronically.

- A complete Phase I and Phase II application package must be mailed together in a single envelope or box.

- Review the **Fast Track Reminder Sheet** before submitting the application.

- Specify in the Phase I application clear, appropriate measurable goals (milestones) that should be achieved prior to initiating Phase II. Failure to provide clear, measurable goals may be sufficient reason for the scientific peer review group to exclude the Phase II application from Fast-Track review. The scientific peer review group will evaluate the goals and may suggest other milestones that should be achieved prior to Phase II funding.

- The Phase I and Phase II applications will receive a single rating. Following the initial peer review, Fast-Track applications will receive secondary review by the advisory council or board of the NIH awarding component that is the potential funding component.

- Submit a concise Product Development Plan (limited to ten pages). Label this section clearly and ***include it as part of the Research Plan (in lieu of the Phase I Final Report)***, after the Significance section and before the Experimental Design and Methods section of the Phase II application. Addressing each of the following areas:

  1. Company information: including size; specialization area(s); products with significant sales; and history of previous Federal and non-Federal funding, regulatory experience, and subsequent commercialization (see Section III of this solicitation for definition of "commercialization").
  2. Value of SBIR/STTR project, including lay description of key technology objectives, current competition, and advantages compared to competing products or services.
  3. Commercialization plans, milestones, target dates, market analyses of market size, and estimated market share after first year sales and after five years.
  4. Patent status or other protection of project intellectual property.

Applicants are ENCOURAGED to seek commitment(s) of funds and/or resources from an investor or partner organization for commercialization of the product(s) or service(s) resulting from the SBIR/STTR grant.

Before submitting applications under "Fast-Track," applicant small business concerns and investigators are strongly encouraged to consult with the NIH program staff named in the table "Awarding Component/Agency Contact Information."

VII. CONSIDERATIONS

A. AWARDS

The approximate number of Phase I grant awards to be issued under this solicitation are:

NIH	900 SBIR awards 100 STTR awards
CDC	15 awards
FDA	2 awards

The primary award mechanism will be the grant instrument. The average dollar amount of Phase I awards (composed of direct costs, indirect costs, and fixed fee) to be issued under this solicitation is estimated to be approximately $100,000. The average dollar amount of Phase II awards (composed of direct costs, indirect costs, and fixed fee) to be issued to continue the research or R&D efforts initiated in Phase I, is estimated to be approximately $750,000 for SBIR awards and $500,000 for STTR awards.

B. REPORTS

NIH requires that SBIR/STTR grantees submit the following reports within 90 days of the end of the grant support period unless an extension is granted by the Grants Management Office (GMO):

- Financial Status Report (OMB 269)
- Final Progress Report (no form)
- Final Invention Statement and Certification (HHS 568)
- Annual Invention Utilization Reports

Failure to submit timely final reports may affect future funding to the organization or awards with the same Principal Investigator.

Final Financial Status Report (FSR) (OMB 269)

As stated in the *NIH Grants Policy Statement*, October 1998, Part II, pages 83-84, a Financial Status Report (OMB 269) must be submitted within 90 days of the expiration date. Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the grantee 0rganization.

The FSR 269 form is available electronically at http://www.whitehouse.gov/OMB/grants/index.html. FSRs may be transmitted electronically to the NIH's Office of Financial Management (OFM), which, for this purpose, is equivalent to submission to the GMO. Information about the electronic transmittal of FSRs may be obtained from OFM at (301) 496-5287. Otherwise, the Financial Status Report may be mailed to:

Government Accounting Branch
Office of Financial Management
National Institutes of Health
31 Center Drive, Room B1B05A, MSC 2050
Bethesda, MD 20892-2050

Prior to submitting FSRs to NIH, grantees must ensure that the information submitted is accurate, complete, and consistent with the grantee's accounting system. The signature of the authorized institutional official on the FSR certifies that the information in the FSR is correct and complete and that all outlays and obligations are for the purposes set forth in grant documents, and represents a claim to the Federal Government. *Filing a false claim may result in the imposition of civil or criminal penalties*.

Final Progress Report

NOTE: A Phase I Final Report is required for all Phase II applications. Specific instructions for submission of the Phase I Final Report are in the Phase II Grant Application kit.

However, if a Phase II application will not be submitted within 90 days of the Phase I project period end date, then submit one copy of the Phase I Final Report to the Grants Management Office of the Awarding Component within 90 days of the termination of the Phase I grant.

The Final Progress Report may be typed on plain white paper and should include, at a minimum:

- Beginning and end dates for the period covered by the SBIR/STTR Phase I grant.
- Key personnel who worked on the project during that period (include titles, dates of service, and number of hours devoted to the project).
- Summary of the specific aims of the Phase I grant.
- Succinct account of published and unpublished results, indicating progress toward achievement of the originally stated aims.
- List of titles and complete references to publications, manuscripts accepted for publication, patents, invention reports and other printed materials, if any, that resulted from the Phase I.

The recommended length for the *narrative portion is 10 pages*.

Final Invention Statement and Certification

The grantee must *submit to the awarding component a Final Invention Statement and Certification (HHS-568)*, whether or not an invention(s) results from work under the grant. The final invention statement/certification must be signed by the Principal Investigator and an authorized institutional official and must list all inventions that were conceived or first actually reduced to practice during the course of work under the project, from the original effective date of support through the date of expiration or termination, whether or not previously reported. If there were no inventions, the statement should indicate "None."

IMPORTANT: All inventions made in the course of, or under, any NIH research grant, including SBIR/STTR awards, must be promptly and fully disclosed to NIH within 2 months after the inventor provides written disclosure to the grantee's authorized official.

The *disclosure must be in writing*. Identify the applicable grant and the name of the inventor(s), and provide a complete technical description and other information as required by 37 CFR 401.14(c)(1) (see "Administrative Requirements Availability of Research Results: Publications and Intellectual Property Rights, Including Unique Research Resources" for the full text of the clause).

In addition to immediate invention disclosure, each application for competing or non-competing continuation support of an NIH grant-supported research project must include either a listing of all inventions conceived or reduced to practice during the preceding budget period or a certification that no inventions were made during the applicable period.

Annual Utilization Report

The grantee must also submit an annual utilization report when the grantee has elected title to an invention or when royalties or licensing fees are generated for inventions that are not patented. NIH has developed an optional online Extramural Invention Information Management System, known as "IEdison," to facilitate grantee compliance with the disclosure and reporting requirements of 37 CFR 401.14(h) (http://www.iedison.gov). *Information from these reports is not made publicly available*. For additional information on IEdison, see Section D below.

A summary of grantee/contractor invention responsibilities, which provides information on time limits placed by law and identifies specific invention reporting actions that must be taken, is provided at the end of this solicitation and is also available on the internet at http://www.iedison.gov/timeline.html.

C. PAYMENT SCHEDULE

Once an SBIR/STTR grant is awarded, the grantee will receive information and forms from the Payment Management System of the HHS regarding requests for cash, manners of payment, and associated reporting requirements. Payment may be made on a cost-reimbursement or advance basis.

D. LIMITED RIGHTS INFORMATION AND DATA

Proprietary Information

Information contained in unfunded grant applications will remain the property of the

applicant. The Government may, however, retain copies of all applications. Public release of information in any application will be subject to existing statutory and regulatory requirements.

If proprietary information provided in an application constitutes trade secrets or proprietary commercial or financial information, confidential personal information or data affecting the national security, it will be treated in confidence, to the extent permitted by law, *provided this information is clearly identified by the appropriate page numbers under the Notice of Proprietary Information on the Face Page of the SBIR/STTR grant application form*. Any other notice may be unacceptable to the Government and may constitute grounds for return of the application without further consideration and without assuming any liability for inadvertent disclosure.

Title to Equipment and Supplies

Title to equipment and supplies acquired by a for-profit organization as a grantee or subcontractor under a grant awarded by the agencies participating in this solicitation, shall vest, upon acquisition, in the grantee or subcontractor, respectively.

Rights to Data Developed Under SBIR/STTR Funding Agreement

Rights to data, including software developed under the terms of any funding agreement resulting from a grant application submitted in response to this solicitation, shall remain with the grantee, except that the Government shall have the limited right to use such data for internal Government purposes and shall not release such data outside the Government without permission of the grantee for a period of four years from completion of the project from which the data were generated.

Copyrights

The grantee may normally copyright and publish (consistent with appropriate national security considerations, if any) material developed with PHS support. The awarding component receives a royalty-free license for the Federal Government and requires that each publication contain an acknowledgment of agency support and disclaimer statement, as appropriate. An acknowledgment shall be to the effect that *"This publication was made possible by grant number _____ from (NIH/CDC/FDA awarding component)"* OR *"The project described was supported by grant number _____ from (NIH/CDC/FDA awarding component). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the (NIH/CDC/FDA awarding component)."*

Inventions

Any invention first conceived for reduced to practice with award funds must be reported to the NIH. *The inventor must report the discovery to the grantee organization promptly*. Within two months of the inventor's initial report to the grantee organization, the organization must report the invention to the NIH's Extramural Invention Reporting and Technology Resources Branch of the Office of Policy for Extramural Research (see address in "Patents" section below). This should be done prior to any publication or presentation of the invention at an open meeting, since failure to report at the appropriate time is a violation of 35 USC 202, and may result in loss of the rights of the small business concern, inventor, and Federal Government in the invention. All foreign patent rights are immediately lost upon publication or other public disclosure unless a United States patent application is already on file. In addition, statutes preclude obtaining valid United States patent protection after one year from the date of a publication that discloses the invention.

The reporting of inventions by the grantee organization to the NIH can be accomplished by submitting paper documentation, including fax, or electronically through the NIH Interagency Edison (IEdison) Invention Reporting System. Use of the IEdison system satisfies all mandated invention reporting requirements and access to the system is through a secure interactive Web site (http://www.iedison.gov) designed to ensure that all information submitted is confidential.

In addition to fulfilling reporting requirements, IEdison notifies the user of future time-sensitive deadlines with enough lead-time to avoid the possibility of loss of patent rights due to administrative oversight. IEdison can accommodate the invention reporting needs of all organizations. For additional information about this invention reporting and tracking system, *visit the IEdison home page cited above*

or contact Edison via e-mail at edison@od.nih.gov.

Patents

Small business concerns normally retain the principal worldwide patent rights to any invention developed with Government support. Under existing regulations, 37 CFR 401, the Government receives a royalty-free license for Federal Government use, reserves the right to require the patent-holder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it substantially in the United States. The applicant small business concern is *strongly encouraged to obtain information about additional requirements imposed by 37 CFR 401 from local counsel or from*:

Extramural Invention Reporting and Technology Resources Branch
Office of Policy for Extramural Research
National Institutes of Health
6701 Rockledge Drive, Room 3190, MSC 7750
Bethesda, MD 20892-7750
Phone: (301) 435-1986; Fax: (301) 480-0272
Email: gs60a@nih.gov or edison@od.nih.gov.

To the extent authorized by 35 U.S.C. 205, the Government will not make public any information disclosing a Government-supported invention for a four-year period from the date of disclosure to allow the grantee a reasonable time to file a patent application, nor will the Government release any information that is part of that patent application.

Research Tools/Unique Research Resources

It is the policy of the NIH to make available to the public the results and accomplishments of the activities it funds. Restricted availability of unique research resources, upon which further studies are dependent, can impede the advancement of research and delivery of medical care. Notices in the *NIH Guide for Grants and Contracts (Vol. 23, No. 26*, July 15, 1994, http://grants.nih.gov/grants/guide/1994/94.07.15/notice-public-health007.html) and the *NIH Grants Policy Statement* (http://grants.nih.gov/grants/policy/nihgps/part_ii_5.htm) fully explain the policy regarding the distribution of research resources developed with NIH funds.

The NIH encourages the commercialization of research products and allows grantee organizations to make materials available to others for commercial purposes with appropriate restrictions and licensing terms. Where the product of research developed with Federal funding is a patentable but unpatented research product, the terms of a license must be no more restrictive than they would have been if the product had been patented.

E. PROFIT OR FEE

A reasonable fixed fee is available to small business concerns receiving awards under the SBIR/STTR program. The fee is not a "cost" item and may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work. However, the amount of the fee approved by the agencies participating in this solicitation normally will not exceed 7% of total costs (direct and indirect) for each phase (I and II) of the project. *The fixed fee applies solely to the small business concern (grantee organization) receiving the SBIR/STTR award and not to any other participant in the project*. However, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.

F. JOINT VENTURES AND LIMITED PARTNERSHIPS

Joint ventures and limited partnerships are eligible provided the entity created qualifies as a small business concern in accordance with the definition in Section III.

G. AMERICAN-MADE EQUIPMENT AND PRODUCTS

When purchasing equipment or a product under the SBIR/STTR award, the small business concern should purchase only American-made items whenever possible.

H. TERMS AND CONDITIONS OF AWARD

Upon acceptance of a grant award, the grantee must comply with the terms and conditions contained or referenced in the Notice of Grant Award document. These terms and conditions, constituting legal requirements imposed on an awardee by statute, regulations, administrative policy, or the award document itself, are either "standard" or "special" as follows:

Standard Terms and Conditions. Those that are required by policy to be incorporated by reference in Notices of Grant Award through citations of specific documents that contain requirements applicable to the grant.

Special Terms and Conditions. Those that are judged necessary to attain the objectives for which the grant is being awarded, facilitate post-award administration, conserve grant funds, or otherwise protect the interests of the Federal Government. They are stated in full on the Notice of Grant Award.

Grant awards must be administered in accordance with the *NIH Grants Policy Statement* (http://www.nih.gov/grants/policy/nihgps) and with the following regulations and policy:

9 CFR 1,2,3	Animal Welfare
37 CFR 401	Rights to Inventions Made by Non-profit Organizations and Small Business Firms under Government Grants, Contracts, and Cooperative Agreements
42 CFR 52	Grants for Research Projects
45 CFR 46	Protection of Human Subjects
45 CFR 74	Administration of Grants
45 CFR 80	Nondiscrimination Under Programs Receiving Federal Assistance Through DHHS Effectuation of Title VI of the Civil Rights Act of 1964.
45 CFR 84	Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance
45 CFR 91	Nondiscrimination on the Basis of Age in Programs and Activities Receiving or Benefiting from Federal Financial Assistance
P.L. 99-158	Public Health Service Policy on Humane Care and Use of Laboratory Animals Section 495 "Animals in Research"
P.L. 100-690	Drug-Free Workplace Act of 1988 Title V, Subtitle D

I. ADDITIONAL INFORMATION

This Omnibus Solicitation is intended for informational purposes and reflects current planning. If there is *any inconsistency between the information contained herein and the terms of any resulting SBIR/STTR funding agreement, the terms of the funding agreement are controlling*.

Prior to award of an SBIR/STTR funding agreement, the Government may request the applicant small business concern to submit certain organizational, management, personnel, and financial information to ensure responsibility of the applicant organization.

This Omnibus Solicitation is not an offer by the Government and does not obligate the Government to make any specific number of awards. Awards under the SBIR/STTR program are contingent upon the scientific and technical merit and potential for commercialization of an application and the availability of funds for research and development. The Government is not responsible for any monies expended by the applicant organization before award of any funding agreement.

If an award is made pursuant to a grant application submitted in response to this Omnibus Solicitation, the grantee may be required to certify that it has not previously been, nor is currently being, paid for essentially equivalent work by any agency of the Federal Government. See Section III for the definition of "essentially equivalent work." If an award is made under this Omnibus Solicitation for a project, some of whose elements are being or will be supported by another Federal agency, the awarding component and the applicant

organization will negotiate a budget that reflects the elimination of any overlapping support.

VIII. SCIENTIFIC AND TECHNICAL INFORMATION SOURCES

Health science research literature is available at academic and health science libraries throughout the United States. Information retrieval services are available at these libraries and Regional Medical Libraries through a network supported by the National Library of Medicine. A list of Regional Medical Libraries and information about network services may be requested from the Public Information Office, National Library of Medicine, Bethesda, MD 20894, Phone: (301) 496-6308. Other sources that provide technology search and/or document services include the organizations listed below. They should be contacted directly for service and cost information.

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
(703) 487-4600

National Technology Transfer Center
Wheeling Jesuit College
316 Washington Avenue
Wheeling, WV 26003-6295
(800) 678-6882 (toll-free US)

Mid-Atlantic Technology Applications Center
University of Pittsburgh
823 William Pitt Union
Pittsburgh, PA 15260
(800) 257-2725 (toll-free US)
(412) 648-7003 (Fax)

Mid-Continent Technology Transfer Center
The Texas A&M University System
College Station, TX 77843-3401
(409) 845-8762
(409) 845-3559 (Fax)

Far West Regional Technology Transfer Center
University of Southern California
3716 South Hope Street, Suite 200
Los Angeles, CA 90007-4344
(800) 642-2872 (CA only)
(800) 872-7477 (outside CA)
(213) 746-9043 (Fax)

Southern Technology Applications Center
University of Florida
College of Engineering, Box 24
One Progress Boulevard
Alachua, FL 32615
(904) 462-3913
(800) 225-0308 (outside FL)

Center for Technology Commercialization
Massachusetts Technology Park
100 North Drive
Westborough, MA 01581
(508) 870-0042

Great Lakes Industrial Technology Center
25000 Great Northern Corporate Center
Suite 260
Cleveland, OH 44070-5310
(216) 734-0094
(216) 734-0686 (fax)

IX. MODEL AGREEMENT FOR ALLOCATION OF RIGHTS

The STTR legislation (Public Law 102-564, as amended) and the STTR Policy Directive of the Small Business Administration (SBA), dated August 10, 1993, require that agencies participating in the STTR program provide guidance for allocating between small business concerns and research institutions intellectual property rights and rights, if any, to carry out follow-on research, development or commercialization. Included in this solicitation, is the guidance as approved by the SBA and the Office of the General Counsel, HHS. The document, entitled "Model Agreement, Small Business Technology Transfer (STTR) Program, Allocation of Rights in Intellectual Property and Rights to Carry Out Follow-on Research, Development, or Commercialization," may be photocopied freely. The parties to the Agreement are advised that this "model" may be revised through negotiation between the small business concern and the single, "partnering" research institution.

The *Agreement is a requirement to receive support under the STTR program. Therefore, by signing the Face Page of the grant application, the Official Signing for Applicant Organization (small business concern) certifies that the Agreement with the research institution will be effective at the time of award*. A copy of the Agreement must be furnished upon request of the NIH awarding component.

X. GRANTS: PROGRAM DESCRIPTIONS AND RESEARCH TOPICS

The research topics shown in this solicitation represent program areas that may be of interest to applicant small business concerns in the development of projects that have potential for commercialization. Small business concerns are encouraged to submit SBIR/STTR grant applications in these areas.

However, SBIR and STTR (applicable to NIH only) grant applications will be accepted and considered in any area within the mission of the awarding components identified in this solicitation.

Applicants are encouraged to query program administrators periodically via email to learn of new or emerging scientific interests of the NIH, CDC, and FDA awarding components. Additional information on each of the awarding components and their research interests is available electronically on the home pages indicated throughout this section of the solicitation.

The Fogarty International Center, which provides support only for conferences, postdoctoral fellowships for research in the United States and abroad, and senior scientist exchanges between the United States and other countries, does not participate in the SBIR/STTR program.

OFFICE OF PUBLIC HEALTH AND SCIENCE, OFFICE OF RESEARCH INTEGRITY (ORI)

ORI administers Public Health Service (PHS) research integrity activities on behalf of the Secretary of Health and Human Services (HHS) with the exception of the regulatory research integrity activities of the Food and Drug Administration. ORI facilitates a collaborative system for promoting integrity in biomedical and behavioral research supported or conducted by agencies of the U.S. Public Health Service (PHS). The system involves cooperative efforts among individual scientists, research institutions, and PHS agencies. For additional information about ORI visit http://ori.hhs.gov.

Development and dissemination of quality educational resources in the responsible conduct of research, for research professionals and trainees. Topics of interest include:

A. **Data Acquisition, Management, Sharing, and Ownership**. Accepted practices for acquiring and maintaining research data. Proper methods for record keeping and electronic data collection and storage in scientific research. Includes defining what constitutes data; keeping data notebooks; data selection, retention, sharing, ownership, and analysis; data as legal documents and intellectual property, including copyright laws. Identification and understanding of existing federal and local policies relevant to the topic.

B. **Mentor/trainee Relationships**. The responsibilities of mentors and trainees in pre-doctoral and postdoctoral research programs. Includes the role of a mentor, responsibilities of a mentor, conflicts between mentor and trainee, collaboration and competition, selection of a mentor, and abusing the mentor/trainee relationship. Identification and understanding of existing federal and local policies relevant to the topic.

C. **Publication Practices and Responsible Authorship**. The purpose and importance of scientific publication, and the responsibilities of the authors. Includes topics such as collaborative work and assigning appropriate credit, acknowledgements, appropriate citations, repetitive publications, fragmentary publication, sufficient description of methods, corrections and retractions, conventions for deciding upon authors, authors' responsibilities, and the pressure to publish. Identification and understanding of existing federal and local policies relevant to the topic.

D. **Peer Review**. The purpose of peer review in determining merit for research funding and publications. Includes topics such as, the definition of peer review, impartiality, how peer review works, editorial boards and ad hoc reviewers, responsibilities of the reviewers, privileged information and confidentiality. Identification and understanding of existing federal and local policies relevant to the topic.

E. **Collaborative Science**. Research collaborations and issues that may arise from such collaborations. Includes topics such as setting ground rules early in the collaboration, avoiding authorship disputes, and the sharing of materials and

information with internal and external collaborating scientists. Identification and understanding of existing federal and local policies relevant to the topic.

F. **Human Subjects**. Issues important in conducting research involving human subjects. Includes topics such as the definition of human subjects research, ethical principles for conducting human subjects research, informed consent, confidentiality and privacy of data and patient records, risks and benefits, preparation of a research protocol, institutional review boards, adherence to study protocol, proper conduct of the study, and gender, minority, and children's research issues. Identification and understanding of existing federal and local policies relevant to the topic.

G. **Research Involving Animals**. Issues important to conducting research involving animals. Includes topics such as definition of research involving animals, ethical principles for conducting research on animals, federal regulations governing animal research, institutional animal care and use committees, and treatment of animals. Identification and understanding of existing federal and local policies relevant to the topic.

H. **Research Misconduct**. The meaning of research misconduct and the regulations, policies, and guidelines that govern research misconduct in PHS-funded institutions. Includes topics such as fabrication, falsification, and plagiarism; error vs. intentional misconduct; institutional misconduct policies; identifying misconduct; procedures for reporting misconduct; protection of whistleblowers; and outcomes of investigations, including institutional and federal actions. Identification and understanding of existing federal and local policies relevant to the topic.

I. **Conflict of Interest and Commitment**. The definition of conflicts of interest and how to handle conflicts of interest. Types of conflicts encountered by researchers and institutions. Includes topics such as conflicts associated with collaborators, publication, financial conflicts, obligations to other constituencies, and other types of conflicts. Identification and understanding of existing federal and local policies relevant to the topic.

For additional information on research topics, contact:

Anita Ousley, Ph.D.
Office of Research Integrity
Phone: (301) 443-5300; Fax: (301) 443-5351
Email: aousley@osophs.dhhs.gov

For administrative and business management questions, contact:

Ms. Kathleen Howe
Grants Management Specialist
National Institute of Neurological Disorder and Stroke
6001 Executive Boulevard, Room 3266
Bethesda, MD 20892
(301) 496-7392; Fax: (301) 402-0219
Email: kh52x@nih.gov

NATIONAL INSTITUTES OF HEALTH (NIH)

The mission of the NIH is to improve human health through biomedical and behavioral research, research training, and communications. The programs of the NIH are oriented principally towards basic and applied scientific inquiry related to the causes, diagnosis, prevention, treatment, and rehabilitation of human diseases and disabilities; the fundamental biological processes of growth, development, and aging; and the biological effects of the environment. In addition, the NIH sponsors training of research personnel; career development of new and established scientists; evaluation and dissemination of new information about medicine and health; construction and renovation of research facilities and provision of other research resources; and improvements in biomedical communications.

To carry out these responsibilities, the NIH is organized into awarding components (Institutes/Centers). Those components that have an extramural element, that is, provide funds for research and research training activities in organizations external to the NIH, are shown below. The NIH makes every effort to finance worthy proposals, including the co-funding of such proposals by one or more awarding components having relevance in the projects.

NATIONAL INSTITUTE ON AGING (NIA)

The NIA supports biomedical, behavioral, and social research and research training on the aging process as well as on the diseases and other special problems and needs of older people. It supports grant research under four established programs: Biology of Aging, Behavioral and Social Research, Neuroscience and Neuropsychology of Aging and Geriatrics.

Examples of research topics within the mission of the NIA that may be of interest to small businesses are shown below. These listings illustrate the range of areas that are of interest to the NIA and are not intended to be exhaustive.

For additional information about areas of interest to the NIA, please visit our home page at http://www.nih.gov/nia.

Biology of Aging

Research on the physiology, molecular, and cellular basis of aging processes. NIA also has responsibility for maintaining existing resources and developing new resources for aging research, such as populations of well-characterized animals and specific cell lines, for example, human fetal lung fibroblasts. The Biology of Aging Program includes the following eight programmatic areas: Animal Models; Cell Structure and Function; Cardiovascular Biology; Genetics; Immunology; Metabolic Regulation; and Musculoskeletal Biology.

ANIMAL MODELS. The objective of the Animal Models Program is to identify and develop new animal models, both mammalian and lower organism, for use in aging research. This includes research on rats, mice, rabbits, non-human primates, insects, nematodes and yeast. Mutant and genetically-engineered rodent models of both normal aging and specific age-related pathologies are of particular interest.

Dr. Nancy Nadon
(301) 496-0181, Fax: (301) 402-0010
Email: nn37a@nih.gov

A. *Systems Branch*.

CARDIOVASCULAR BIOLOGY. The objectives of the Cardiovascular Biology Program are to support basic reserch on age related changes in cardiovascular function, e.g. gene expression, and factors affecting cell death in heart tissue.

Dr. David Finkelstein
(301) 496-6402, Fax: (301) 402-0010
Email: df18s@nih.gov

ENDOCRINOLOGY. The purpose of the endocrinology of aging program is to support basic molecular and cellular research into the causes and effects of age-related changes in the endocrine system of humans and various animal models. Areas of investigation in this program include age-related changes in hormone production, metabolism, and action, diabetes, reproductive aging – male and female, biology of menopause, animal models of menopause, endocrine connections to menopause-related pathology in non endocrine systems, age-related changes in endocrine control of prostate growth, and endocrine aspects of age-dependent tumors.

Dr. Frank Bellino
(301) 496-6402, Fax: (301) 402-0010
Email: fb12a@nih.gov

IMMUNOLOGY. Changes in the immune system of older people may contribute to the increased incidence of infection and cancer in the elderly. Research directed towards understanding the age-related regulation of immune function in health and disease is supported by BAP. Areas of investigation in this program include regulation of lymphocyte proliferation, regulation of immune specificity, response of immune system to biochemical stimuli, autoimmune disease and other immunopathology, endocrine and neuroendocrine control of immune function, molecular basis of the age-related decline in immune function, and interventions to retard and/or correct age-related decline in immune function.

Rebecca Fuldner
(301) 496-6402, Fax: (301) 402-0010
Email: fuldnerr@mail.nih.gov

MUSCULOSKETAL BIOLOGY. The age-related change of function of various physiologic systems often negatively impacts the health of the elderly. The purpose of this program is to support high quality basic molecular and cellular research to understand the causes and

effects of these changes, thereby encouraging the development of preventative and interventional strategies to extend the health span of the elderly. Areas of investigation in this program include age-related changes in osteoblast and osteoclast function and bone matrix, age-related changes in muscle structure and function, age-related changes in cartilage, connective tissue and skin, molecular mechanisms of the above age-related changes, and the molecular basis of osteoporosis and osteoarthritis.

Jill Carrington
(301) 496-6402, Fax: (301) 402-0010
Email: jc189n@nih.gov

B. *Genetics and Cell Biology Branch*

CELL STRUCTURE AND FUNCTION. The objectives of the Cell Structure and Function Program are to support research on the molecular basis of age-related changes in signal transduction mechanisms, microenvironment – ECM, cell senescence/apoptosis/cancer, telomeres, and membranes and membrane receptors.

GENETICS. The objectives of the Genetics Program are to support research on identification and characterization of longevity assurance genes (LAGs) and senescence assurance genes (SAGs, genome stability, genomics, mouse mutagenesis; single nucleotide polymorphisms/genetic epidemiology, and Werner's syndrome.

Dr. Anna McCormick
(301) 496-6402, Fax: (301) 402-0010
Email: am38k@nih.gov

METABOLOIC REGULATION. Areas of investigation in the Metabolic Regulation Program include nutrition/metabolism, age-related changes in mitochondrial function/mitochondrial dysfunction, mechanism of life span extension by caloric restriction, and generation of free radicals and oxidative stress.

Dr. David Finkelstein
(301) 496-6402, Fax: (301) 402-0010
Email: df18s@nih.gov

For examples of areas of interest, see NIA Topics.pdf.

Behavioral and Social Research

Research on the psychological, social, cultural, demographic and economic factors that affect the process of growing old; the place of older people in society; unique problems facing the elderly; and the maintenance of health and effective functioning in the middle and later years. Special emphasis is placed on neglected groups of older people including, for example, oldest old, older minority populations, older women (including topics related to menopause), older adults living in rural areas, and older adults with developmental disabilities. For examples of areas of interest, see NIA Topics.pdf.

A. *Individual Behavioral Process Branch*. Supports research and training on biopsychosocial processes linking health and behavior, cognitive functioning, human factors, and integrative approaches to the study of social, psychological, and physiological influences on health and well-being over the life course. Personality and social/interpersonal relationships are investigated as causal variables, and as mediators or moderators of the relationships between social/structural characteristics and health outcomes.

BEHAVIORAL MEDICINE AND INTERVENTIONS. Major research topics include: (1) disease recognition, coping and management, including physiological consequences of life stresses and burdens; and (2) social, behavioral and environmental interventions for health promotion, disease prevention, and disability postponement.

Dr. Marcia Ory
(301) 402-4156, Fax: (301) 402-0051
Email: mo12x@nih.gov

COGNITIVE AGING. Supports research on changes in cognitive functioning over the life course. Studies are encouraged that: (1) examine the influence of contexts (behavioral, social, cultural, and technological) on the cognitive functioning and life performance of aging persons; (2) investigate the effects of age-related changes in cognition on activities of daily living, social relationships, and health status, and (3) develop strategies for improving everyday functioning through cognitive interventions. Major research topics include: higher-order cognitive processes (e.g.,problem-solving, decision-

making), social cognition, memory strategies, perceptual skills, and reading and speech comprehension. Research is also welcomed that explores the role of individual difference factors in cognitive functioning (e.g., motivation, self-efficacy, beliefs about aging, emotions, sensory limitations, experience and expertise).

Dr. Daniel Berch
(301).594.5942, Fax: (301) 402-0051
Email: berchd@nia.nih.gov

PSYCHOLOGICAL DEVELOPMENT AND INTEGRATIVE SCIENCE. Promotes research that applies an integrative approach to the study of health, behavior, stress and coping, and well-being over the life course. Studies are encouraged that combine diverse levels of analysis and examine reciprocal interactions among these levels. Examples include the effects of sociocultural, psychological (social, personality), biological, and genetic processes on behavioral and functional aging. In addition, research exploring factors at a single level that influence aging are welcomed.

Dr. Daniel Berch
(301).594-5942, Fax: (301) 402-0051
Email: berchd@nia.nih.gov

B. *Population and Social Sciences Branch*. Supports research and training on the antecedents and impact of changing social, demographic, economic, and health characteristics of the older population. Research on the consequences of particular health care organizations and settings, and studies of the effects of other social institutions upon the health, well-being, and functioning of people in the middle and later years are supported. Comparative research is often appropriate, and interconnections with individual behavioral processes are encouraged.

DEMOGRAPHY AND EPIDEMIOLOGY. Embraces such topics as medical and bio-demography; changes in the age-structure of populations, as well as studies on the prevalence and incidence of disease and disability, and age trajectories of health; life expectancy and active life expectancy; forecasting functioning, disability, morbidity, and mortality; migration and geographic concentrations of older people; rural-urban comparisons; distributions of health services and the long-term care system; race, ethnic, and socioeconomic variations; genetic epidemiology and population genetics.

Dr. Rose Maria Li
(301).496-3138
Email: lir@nia.nih.gov

Dr.Jennifer Harris
(301).496-3138
Email: harrisje@nia.nih.gov

Ms. Angie Chon-Lee
(301).496-3138
Email: chon-lea@nia.nih.gov

HEALTH AND RETIREMENT ECONOMICS. Concentrates on the economics of aging, including but not limited to economic and health antecedents and consequences of work and retirement; pensions and savings; health insurance and health care expenditures; Medicaid, Medicare, and Social Security; interrelationships between health and economic status, including issues related to wealth, poverty, productivity, human capital development, and economic development; the economic costs of disability; cost-effectiveness of interventions; taxation policies on older people; cross-national comparisons.

Dr. Rose Maria Li
(301).496-3138
Email: lir@nia.nih.gov

HEALTH AND SOCIAL INSTITUTIONS. Encourages research on the impact of a wide range of formal health care and related services, with particular emphasis on long-term care systems and settings and on the health and well-being of older persons. It also examines hoe social institutions (e.g., work, family, religion, community, living arrangements influence health outcomes in the later years and the ways in which people influence and are influenced by the network of cultural and social institutions surrounding them.

Dr. Sidney M. Stahl
(301) 402-4156, Fax: (301) 402-0051
Email: ss333h@nih.gov

Neuroscience and Neuropsychology of Aging

Research on age-related changes in the brain or nervous system in the context of other age-related physiological or homeostatic regulator changes (e.g., endocrine, dietary, immune, disease states); degenerative processes or pathological changes in the aging brain in the context of understanding normal age-related changes; and the sensory, perceptual and cognitive processes and changes that occur with aging as related to their underlying biological mechanisms. An important component of this program is the support of studies on Alzheimer's disease and related dementias of aging.

Dr. Neil Buckholtz
(301) 496-9350, Fax: (301)496-1494
Email: nb12s@nih.gov

Dr. Judith Finkelstein
(301) 496-9350, Fax: (301)496-1494
Email: jf119k@nih.gov

Dr. Andrew Monjan
(301) 496-9350, Fax: (301)496-1494
Email: am39m@nih.gov

Dr. Molly Wagster
(301) 496-9350, Fax: (301)496-1494
Email: mw203d@nih.gov

Dr. Brad Wise
(301) 496-9350, Fax: (301)496-1494
Email: bw86y@nih.gov

For examples of areas of interest, see NIA Topics.pdf.

Geriatrics

The Geriatrics Program supports research on prevention, treatment, and diagnosis of clinical problems that occur predominantly among older persons or that are associated with increased morbidity and mortality in older people; investigations of clinical problems associated with nursing homes and other sites of long-term care for frail older persons.

Dr. Stanley Slater
(301) 496-6761, Fax: (301) 402-1784
Email: ss81z@nih.gov

Dr. Sherry Sherman, Ph.D.
(301) 435-3048, Fax: (301) 402-1784
Email: ss80t@nih.gov

Dr. Chhanda Dutta
(301) 435-3048, Fax: (301) 402-1784
Email: cd23z@nih.gov

Dr. Rosemary Yancik
(301) 496-5278, Fax: (301) 402-1784
Email: ry3e@nih.gov

For examples of areas of interest, see NIA Topics.pdf.

Other Research Topic(s) Within Mission of Institute

For additional information on research topics, contact:

Dr. Miriam F. Kelty
National Institute on Aging
Gateway Building, Suite 2C218
7201 Wisconsin Ave., MSC 9205
Bethesda, MD 20892-9205
(301) 496-9322; Fax: (301) 402-2945
Email: mk46u@nih.gov

For administrative and business management questions, contact:

Ms. Linda Whipp
Grants Management Officer
National Institute on Aging
Gateway Building, Room 2N212
7201 Wisconsin Ave., MSC 9205
Bethesda, MD 20892
(301) 496-1472; Fax: (301) 402-3672
Email: lw17m@nih.gov

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

The NIAAA supports research on the causes, prevention, control, and treatment of the major health problems of alcohol abuse, alcoholism, and alcohol-related problems. Through its extramural research programs, the NIAAA funds a wide range of basic and applied research to develop new and/or improved technologies and approaches for increasing the effectiveness of diagnosis, treatment, and prevention. The NIAAA also is concerned with strengthening research dissemination, scientific communications, public education, and data collection activities in the areas of its research programs.

For additional information about areas of interest to the NIAAA, please visit our home page at http://www.niaaa.nih.gov.

Pharmaceutical Development for Alcoholism Treatment

Applied and, where appropriate, clinical research on pharmacologic agents for use in the treatment or medical management of alcoholism, disorders resulting from alcoholism, the improvement and refinement of drugs currently available for therapeutic purposes, or drugs suitable for use in basic research studies on alcohol addiction. For examples of areas of interest, see NIAAA Topics.pdf.

For clinical questions, contact:
Raye Litten, Ph.D.
(301) 443-0636
Email: rl49g@nih.gov

For pre-clinical questions, contact:
Walter Hunt, Ph.D.
(301) 443-4225
Email: wh30x@nih.gov

Diagnostic Assessment of Alcohol Use Disorders and Comorbidity

Innovative self-report and biochemical approaches to the early identification of alcohol use problems and diagnosis of alcohol use disorders and comorbidity are needed. The research design should include measurements of reliability and validity in appropriate population samples. For examples of areas of interest, see NIAAA Topics.pdf.

John Allen, Ph.D.
(301) 443-0633
Email: ja55o@nih.gov

Treatment of Alcoholism

Development and evaluation of innovative treatment approaches. Development and validation of tools to aid in the clinical management of patients. For examples of areas of interest, see NIAAA Topics.pdf.

Joanne Fertig, Ph.D.
(301) 443-0635
Email: jf75t@nih.gov

Measurement of Alcohol Consumption/Impairment

Development of new methods for quantitative measurement of alcohol consumption, development of new and more accurate cost-effective technological approaches for non-invasive measurement of blood alcohol concentration, and development of novel approaches to measure and quantify alcohol-induced impairment of human performance. For examples of areas of interest, see NIAAA Topics.pdf.

Raye Litten, Ph.D.
(301) 443-0636
Email: rl49g@nih.gov

Prevention

Development and evaluation of innovative prevention/intervention programs, or specific materials for integration into existing programs, which utilize state-of-the-art technology and are based on currently accepted clinical and behavioral strategies. Applicants are strongly encouraged to consult with research methodologists and statisticians to ensure that state-of-the-art approaches to design, analysis, and interpretation of studies under this topic are used. For examples of areas of interest, see NIAAA Topics.pdf.

Kendall Bryant, Ph.D.
(301) 443-8820
Email: kb57c@nih.gov

Training in Alcoholism Assessment and Treatment Techniques

Development of educational materials, including computer-based approaches, for training of health professionals in the use of various assessment techniques and treatment strategies. For examples of areas of interest, see NIAAA Topics.pdf.

Harold Perl, Ph.D.
(301) 443-0788
Email: hp14o@nih.gov

Fetal Alcohol Syndrome (FAS) and Alcohol-Related Birth Defects

FAS is a severe developmental disorder that includes mental retardation, cognitive and behavioral disabilities, and motor impairment.

The NIAAA supports research leading to improved diagnosis and assessment of impairment and disability, as well as the development of tools to enhance academic and daily living skills. For examples of areas of interest, see NIAAA Topics.pdf.

For clinical research questions, contact:
Jan Howard, Ph.D.
(301) 443-1678
Email: jh184h@nih.gov

For basic research questions, contact:
Laurie Foudin, Ph.D.
(301) 443-0912
Email: lf29z@nih.gov

Science Education

The NIAAA Science Education program is intended to: (1) supplement in-service education of health professionals and paraprofessionals with respect to their recognition and treatment of alcohol-related medical problems; (2) stimulate the interest of both precollege and college students, especially among underserved populations, in career opportunities in the biomedical and behavioral sciences generally and the alcohol field specifically; (3) enhance precollege education in the classroom, both directly and via support to teachers, in the life sciences and in education regarding science-related personal and societal challenges; and (4) improve public understanding of science generally and with particular regard to the role of and need for alcohol research. The NIAAA Science Education program complements, but does not duplicate, the education and training components described under other NIAAA topics. For examples of areas of interest, see NIAAA Topics.pdf.

Ms. Dorothea de Zafra
(301) 443-6516
Email: dd128a@nih.gov

Research Tools

The NIAAA supports basic and applied research to develop new or improved tools to enhance laboratory studies on humans and animals. Examples include transgenic animal models, cell lines, new ligands for neuroimaging, and simulators of alcohol impairment. For examples of areas of interest, see NIAAA Topics.pdf.

Laurie Foudin, Ph.D.
(301) 443-0912
Email: lf29z@nih.gov

Other Research Topic(s) Within Mission of Institute

For additional information on research topics, contact:

Dr. Michael Eckardt
National Institute on Alcohol Abuse and Alcoholism
(301) 443-6107; Fax: (301) 443-6077
Email: me25t@nih.gov

For administrative and business management questions, contact:

Ms. Linda Hilley
Grants Management Officer
National Institute on Alcohol Abuse and Alcoholism
(301) 443-4704; Fax: (301) 443-3891
Email: lh67b@nih.gov

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

The NIAID's Division of AIDS, Division of Allergy, Immunology, and Transplantation, and Division of Microbiology and Infectious Diseases fund SBIR/STTR grants on topics related to their mission and activities as described below. Questions on specific research areas may be addressed to the NIAID Branch Chiefs listed below. General questions on the NIAID SBIR programs and on administrative and business management may be addressed to contacts listed at the end of the NIAID section. When possible, *applicants are encouraged to use email* for communication.

For additional information about areas of interest to the NIAID, please visit our home page at http://www.niaid.nih.gov/.

Division of AIDS

The Division of AIDS (DAIDS) supports research on the pathogenesis, natural history, and transmission of HIV and HIV disease, and promotes progress in its detection, treatment, and prevention.

Director: Dr. Jack Killen
(301) 496-0545
Email: jk31e@nih.gov

BIOSTATISTIC RESEARCH BRANCH

Statistical methods in HIV studies.

Chief, Dr: Dennis O. Dixon
(301) 402-2306
Email: dd23a@nihlgov

BASIC SCIENCES PROGRAM

Supports basic and applied research on the causes, diagnosis, and prevention of HIV and AIDS.

Dr. Carl Dieffenbach
(301) 496-0637
Email: wd6u@nih.gov

A. *Epidemiology Branch*. Population-based research of HIV transmission and associated biological, behavioral, and environmental factors including correlation between immunologic and virologic events and clinical outcome trends in natural history; correlation between immunologic and virologic events and clinical outcome; and trends in natural history.

Chief: Dr. Paolo Miotti
(301) 496-9176
Email: pm122m@nih.gov

B. *Pathogenesis Branch*. Molecular and cellular biology, virology, and immunology of virus-host interactions and mechanisms of immunopathogenesis and HIV transmission.

Chief: Dr. Susan Plaeger
(301) 402-9444
Email: sp218p@nih.gov

C. *Targeted Interventions Branch*. Research areas: (1) targeted therapeutics emphasizing under-explored viral and cellular targets; (2) innovative therapeutic strategies including immune-based and gene-based therapies and therapeutic vaccines; (3) translational research for effective therapeutics spanning preclinical discovery to pilot clinical studies in humans; (4) preclinical discovery and development of topical microbicides and other entities for non-vaccine prevention strategies; and (5) animal models for evaluating new therapeutic entities, regimens, and strategies.

Chief: Dr. Nava Sarver
(301) 496-2970
Email: ns18p@nih.gov

VACCINE AND PREVENTION RESEARCH PROGRAM

Supports the development of vaccines and other biomedical and behavioral interventions to prevent AIDS.

Associate Director: Dr. Margaret (Peggy) Johnston
(301) 402-0846
Email: pj7p@nih.gov

A. *Vaccine Clinical Development Branch*. Research areas: (1) coordination of phase I, II, and III domestic and international clinical trials of candidate AIDS vaccines; (2) coordination of the characterization of immune responses in HIV-infected and uninfected immunized volunteers; and (3) coordination of studies to identify, validate, and standardize immunologic and virologic markers for monitoring response of participants in vaccine clinical trials.

Chief: Dr. Jorge Flores
(301) 496-8200
Email: jf30t@nih.gov

B. *Prevention Science Branch*. Coordination and support of epidemiologic and behavioral research on adolescents and adults, and to prevent HIV transmission; and coordination of domestic and international phase I, II, and III clinical trials to evaluate HIV/AIDS prevention strategies, including microbicides, chemoprophylactic agents, and other biomedical and behavioral risk reduction interventions.

Chief: Dr. Rodney Hoff (acting)
(301) 496-6177
Email: rh25v@nih.gov

C. *Preclinical Research and Development Branch*. Support of applied preclinical development of candidate AIDS vaccines, delivery methods, and adjuvants for the prevention of AIDS; promotion and evaluation of safety and efficacy of the prevention modalities, especially novel vaccine concepts identified in preclinical models including trials in non-human primates; genetic and immunologic

variation; and mucosal immunity in SIV, HIV, and SHIV models.

Chief: Dr. James Bradac
(301) 435-3754
Email: jb68k@nih.gov

D. *Vaccine Research Branch*. Support of multidisciplinary research on mechanisms of immunity and pathobiology of HIV and related lentiviruses; and use of information obtained on the mechanism of viral and immune pathogenesis of HIV disease to design and promote novel vaccine strategies for HIV prevention.

Chief: Dr. Carl Dieffenbach (acting)
(301) 496-0637
Email: cd17u@nih.gov

THERAPEUTICS RESEARCH PROGRAM

Develops and oversees research and development of therapies for HIV disease, including opportunistic infections (OI) and cancers, in adults, infants, children, and adolescents

Associate Director, Dr. William Duncan
(301) 496-8210
Email: wd6u@nih.gov

A. *Clinical Research Management Branch*. Management of grants and contracts supporting therapeutic clinical trials.

Chief: Dr. Fred Batzold
(301) 402-0143
Email: fb10c@nih.gov

B. *Drug Development and Clinical Sciences Branch*. Preclinical development of experimental therapies; maintenance of a database of potential anti-HIV and -OI compounds; immunologic, virologic, and pharmacologic research related to the design and conduct of clinical trials.

Chief: Dr. Jonathan Kagan
(301) 402-0131, Fax (301) 480-7843
Email: jk38m@nih.gov

C. *HIV Research Branch*. Clinical research of strategies to treat adult primary HIV infection and complications; strategies to augment HIV immune responses and general host immunity.

Chief: Dr. Carla Pettinelli
(301) 496-0700, Fax (301) 402-3171
Email: cp22n@nih.gov

D. *Opportunistic Infections Research Branch*. Preclinical and clinical research to develop better therapies for treating and preventing HIV opportunistic infections.

Chief: Dr. Barbara Laughon
(301) 402-2304, Fax: (301) 402-3171
Email: bl17u@nih.gov

E. *Pediatric Medicine Branch*. HIV therapies in children and adolescents, strategies to reduce transmission from mother to infant or fetus.

Chief: Dr. James McNamara
(301) 402-2300, Fax: (301) 480-4582
Email: jm74q@nih.gov

Division of Allergy, Immunology, and Transplantation

The Division of Allergy, Immunology, and Transplantation (DAIT) supports studies of the immune system in health and the cause, pathogenesis, diagnosis, prevention, and treatment of disease caused by immune dysfunction.

Director: Daniel Rotrosen, M.D.
(301) 496-1886
Email: dr17g@nih.gov

A. *Office of Epidemiology and Clinical Trials*. Methodologies to design, manage, and analyze clinical research and epidemiologic research of the etiology, prevention, and treatment of asthma, allergy, and autoimmune diseases.

Director: Ernestine Smartt
(301) 496-7353, Fax: (301) 402-2571
Email: es23r@nih.gov

B. *Asthma, Allergy, and Inflammation Branch*. Asthma, atopic dermatitis, hypersensitivity reactions, rhinitis, sepsis, sinusitis, urticaria, molecular basis of hypersensitivity, basic studies of asthma and allergy mechanisms, new therapies for asthma and allergic diseases, epidemiology and prevention, phagocyte biology, and mechanisms of host defense.

Section Chief: Dr. Ken Adams
(301) 496-8973, Fax: (301) 402-2571
Email: ka93x@nih.gov

C. *Basic Immunology Branch*. Origin, maturation, and interactions of immune cells, immune cell receptors, ligands, and cytokine biology, molecular basis of activation, antigen recognition, tolerance, and immune response regulation, hematopoiesis and stem cell biology, enhancement of vaccine effectiveness in neonates and adults and basic immunology of vaccines.

Chief: Dr. Helen Quill
(301) 496-7551, Fax: (301) 402-2571
Email: hq1t@nih.gov

D. *Clinical Immunology Branch*. Autoimmune diseases, primary immune deficiencies (not HIV), basic research of disease mechanisms, immunotherapy of disease processes, disorders mediated by lymphocyte products, and mucosal immunity.

Chief: Dr. Elaine Collier (acting)
(301) 496-7104, Fax: (301) 402-2571
Email: ec5x@nih.gov

E. *Genetics and Transplantation Branch*. Identification and characterization of immune regulation genes and use of this knowledge to potentiate or inhibit immune responses (therapeutic immunomodulatory agents); development of animal models of human diseases; manipulation of the immune response to enhance vaccine efficacy; application of knowledge about the regulation of immune response genes to problems of immune dysfunction, whether native or in transplantation; development and improvement of diagnostic and detection methods for infectious agents from nonhuman species being used for transplantation into humans (xenotransplantation); development and improvement of immunomodulatory agents to prevent and treat immune mediated rejection of nonhuman organs, tissues and cells when transplanted into humans; and clinical trials of new methods to decrease transplant rejection including methods to induce donor specific tolerance.

Chief: Dr. Stephen M. Rose
(301) 496-5598, Fax: (301) 402-2571
Email: sr8j@nih.gov

Division of Microbiology and Infectious Diseases

The Division of Microbiology and Infectious Diseases (DMID) supports research to control diseases caused by all infectious agents, except HIV, through basic investigation of microbial physiology and antigenic structure, pathogenesis, clinical trials of drugs and vaccines, and epidemiologic studies

Director: Dr. Carole Heilman
(301) 496-1884
Email: ch25v@nih.gov

A. *Bacteriology and Mycology Branch*. Bacterial diseases: anthrax, actinomycete infections, enterococcal infections, legionellosis, Lyme disease, nosocomial infections, plague, rickettsial diseases (including Coxiella, Ehrlichia, and Rickettisa), sepsis, staphylococcal infections, urinary tract infections, vector-borne bacterial infections, zoonotic bacterial infections; fungi and fungal diseases: aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, cryptococcosis, histoplasmosis, Pneumocystis carinii, other primary and opportunistic fungal infections; antibacterial and antifungal drug resistance; host-pathogen interactions; genetics, molecular, and cell biology; medical bacteriology and mycology; microbial structure and function; development of vaccines, drugs, and diagnostics; clinical trials of antibacterial and antifungal agents; and application of proteomics and genomics to facilitate advances in the areas listed above.

Chief: Dr. Dennis M. Dixon
(301) 496-7728, Fax: (301) 402-2508
Email: dd24a@nih.gov

B. *Biometry Branch*. Primarily provides consultation on the design, conduct, analysis, and reporting of clinical, population, and laboratory investigations of infectious diseases; analyzes and interprets research data; researches statistical methods and manages a small grant portfolio to develop statistical methods relevant to infectious disease research; develops computer software to analyze data; provides services and consultation for computer programming, data management, and study coordination; and serves on

clinical trial data safety and monitoring boards

Acting Chief: Dr. Mark Vanraden
(301) 496-7065, Fax: (301) 402-0804
Email: mv8e@nih.gov

C. *Clinical and Regulatory Affairs Branch*. Prepares investigational new drug applications for drugs and vaccines developed by DMID contracts and the NIAID Division of Intramural Research and fulfills regulatory requirements of the FDA for all contract-supported DMID clinical studies.

Regulatory Affairs: Ms. Elizabeth Horigan
(301) 402-2126
Email: eh14z@nih.gov

D. *Enteric Diseases Branch*. Research areas: (1) diseases and organisms: astrovirus, Bacteroides, calicivirus, Campylobacter, Clostridium, Crohn's Disease, diarrhea, enterotoxins, Escherichia coli, gastroduodenal disease, ulcers, gastroenteritis, Guillain-Barré, Helicobacter pylori, Listeria, normal flora, commensals, norwalk virus, rotavirus, Salmonella, Shigella, Staphylococcus, Vibrio, Yersinia, Hepatic, hepatitis A, B, C, D, E, G and animal model viruses, transfusion-transmitted virus (TTV), viral hepatitis; (2) basic virology and bacteriology, genome sequencing, natural history and pathogenesis; (3) immunology of infectious diseases including mechanisms of recovery and persistence, protective immune responses and immunopathogenesis in animal models and humans; (4) vaccine research and development to prevent infection and control disease; (5) development and evaluation of adjuvants and vaccine vectors; (6) identification of new drug targets and their use to identify new drugs; (7) immunotherapeutic drug discovery and development; (8) epidemiology and transmission; (9) clinical studies and trials; (10) development of model systems to study infection and disease; and (11) characterization and exploitation of the role of normal flora in disease preventive therapy.

Chief: Dr. Leslye Johnson
(301) 496-7051, Fax: (301) 402-1456
Email: lj7m@nih.gov

E. *Parasitology and International Programs Branch*. Research areas: (1) protozoal infections, amebiasis, cryptosporidiosis, cyclosporiasis, giardiasis, leishmaniasis, malaria, trypanosomiasis, toxoplasmosis, Helminth infections, cysticercosis, lymphatic filariasis, schistosomiasis, onchocerciasis, others (e.g., roundworms, tapeworms, and flukes), Invertebrate vectors/ectoparasites, blackflies, mosquitoes, ticks, snails, mites; (2) parasite biology (genetics, genomics, physiology, and biochemistry); (3) protective immunity, immunopathogenesis, evasion of host responses; (4) clinical and epidemiologic studies of the natural history of tropical and parasitic diseases; (5) research and development of vaccines, drugs, immunotherapeutics, and diagnostics, and (6) vector biology and control; mechanisms of pathogen transmission.

Chief: Dr. Stephanie L. James
(301) 496-2544, Fax: (301) 402-0659
Email: sj13y@nih.gov

F. *Respiratory Diseases Branch*. Research areas: (1) viral respiratory diseases, including those caused by: coronaviruses, influenza, parainfluenza viruses, paramyxoviruses, respiratory syncytial virus; (2) bacterial respiratory diseases, including those caused by chronic obstructive pulmonary disease (Moraxella catarrhalis), cystic fibrosis (Pseudomonas aeruginosa and Burkholderia cepacia), Corynebacterium diphtheriae (diphtheria), groups A and B streptococcus, meningitis (Haemophilus influenzae and Neisseria meningitidis), otitis media, pertussis (Bordetella pertussis), pneumonia (Streptococcus pneumoniae, Mycoplasma pneumoniae, Chlamydia pneumoniae and Klebsiella pneumoniae); (3) Otitis media; (4) mycobacterial diseases, including those caused by: M. tuberculosis (tuberculosis), M. leprae (leprosy), non-tuberculous mycobacterial diseases; (5) development and licensure of vaccines and therapeutic agents for treating and preventing respiratory diseases; (6) maternal immunization; (7) basic research on the pathogenesis, immunity, structural biology, molecular genetics, and genomics of respiratory pathogens; (8) epidemiology and natural history of

respiratory pathogens ; (9) development of better and more rapid diagnostics; and (10) understanding the etiology and long-term health impact of respiratory pathogens in various populations.

Chief (acting): Dr. Ann Ginsberg
(301) 496-5305
Email: ag73i@nih.gov

G. *Sexually Transmitted Diseases Branch*. Development of diagnostics, drugs, topical microbicides, and vaccines; role of STDs in HIV transmission; role of HIV in altering STD natural history; molecular immunology; epidemiologic and behavioral research; adolescents and STDs; STDs and infertility; STDs and adverse outcomes of pregnancy; other sequellae of STDs; Genomics of sexually transmitted pathogens.

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H. *Virology Branch*. Acute viral infections and zoonoses, dengue and other arthropod-borne viral diseases (mosquito-borne encephalitis, including West Nile, yellow fever, etc.), hantaviruses, hemorrhagic fevers (Ebola, Lassa, South African hemorrhagic fevers, etc.), measles, polio, coxsackie virus, and other enteroviruses, poxviruses, rabies, rubella; persisting viral diseases and viruses: adenoviruses, bornaviruses, coronaviruses, herpesviruses, parvoviruses, prion diseases; emergence of viral disease; mechanisms of replication, permissiveness, persistence, and latency; vaccines; immune protection and evasion and viral vectors; epidemiology and viral evolution; structure and function of viruses and viral proteins; molecularly targeted approaches to identify and characterize antiviral targets and agents; chemical design and synthesis of novel antiviral agents; in vitro screening and evaluation of antiviral activity; preclinical therapeutic and some prophylactic evaluations of human viral infections in animal models; clinical trials of vaccines and therapies for viral infections; research of civilian defenses for potential bioterrorist use of viruses; development of rapid diagnostic systems; and chronic fatigue syndrome.

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Other Research Topic(s) Within Mission of Institute

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NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

The NIAMS supports research in arthritis and musculoskeletal and skin diseases. Such research is directed at basic understanding of the causes and development of rheumatic diseases, connective tissue diseases, musculoskeletal and skin disorders and diseases. Basic investigations involve immunology; purine metabolism; skeletal muscle structure, function, metabolism and physiology; the structure, function, production, biochemistry and physiology of collagen, elastin, and other proteins of connective tissue; metabolic and hormonal changes in bone; abnormalities in osteoarthritic cartilage; new treatments for fractures; the biomechanics of normal, arthritic and prosthetic joints; the structure, function, barrier properties, metabolism, and physiology of the skin.

For additional information about areas of interest to the NIAMS, please visit our home page at http://www.nih.gov/niams.

Arthritis and Musculoskeletal and Skin Diseases

A. *Rheumatic Diseases Branch*.
Supports basic and clinical research in the normal function and components of connective tissue and the immune system and their dysregulation in rheumatic, genetic, and inherited diseases of connective tissue. The goals are increased understanding of the etiology and pathogenetic mechanisms involved in rheumatic and degenerative disease of the joints and in the translation of these basic research findings to prevention, diagnosis, and treatment of disease. The research supported by the Program utilizes approaches emanating from relevant areas of genetics, biochemistry, cellular and molecular biology, biophysics, enzymology, immunology, pathology, physiology, behavioral medicine, and epidemiology. For examples of areas of interest, see NIAMS Topics.pdf.

A description of other areas of research under investigation may be found at http://www.nih.gov/niams/grants/ep3.htm.

B. *Musculoskeletal Diseases Branch*.
Supports studies of the skeleton and associated connective tissues. Research areas supported through the Musculoskeletal Diseases Branch include bone diseases, bone biology, and orthopaedic research. Broad areas of interest include skeletal development, metabolism, mechanical properties, and responses to injury. Osteoporosis, a disease afflicting many of the Nation's growing population of older people, is particularly emphasized for investigation under this program. Among other diseases and skeletal disorders under investigation are osteogenesis imperfecta, a genetic disorder that leads to fragile, easily fractured bones; Paget's disease of bone, which results in irregular bone formation and subsequent deformity; genetic disorders of bone growth and development, such as osteopetrosis and the osteochondrodysplasias; vitamin D refractory diseases; and rickets and osteomalacia. Other studies focus on the causes and treatment of acute and chronic injuries, including carpal tunnel syndrome, repetitive stress injury, low back pain and clinical and epidemiological studies of osteoarthritis. The Program supports development of new technologies with the potential to improve treatment of skeletal disorders and facilitate the repair of trauma in the normal skeleton. These include drugs and nutritional interventions, joint replacement, bone and cartilage transplantation, and gene therapy. In addition, bioengineering, sports medicine and musculoskeletal fitness are areas of special research emphasis. For examples of areas of interest, see NIAMS Topics.pdf.

A description of other areas of research under investigation may be found at http://www.nih.gov/niams/grants/ep5.htm

C. *Skin Diseases Branch*.
Supports basic and clinical studies of the skin in normal and disease states. The wide range of skin diseases under study with NIAMS support includes keratinizing disorders such as psoriasis and ichthyosis, atopic dermatitis and other chronic inflammatory skin disorders, the vesiculobullous diseases such as epidermolysis bullosa and pemphigus, acne, and vitiligo. For examples of areas of interest, see NIAMS Topics.pdf.

A description of other areas of research under investigation may be found at: http://www.nih.gov/niams/grants/ep6.htm

Markers of Osteoarthritis

The NIAMS seeks applications for the development and validation of standardized, sensitive assays for osteoarthritis markers in body fluids or tissue specimens. Osteoarthritis is the most prevalent musculoskeletal disorder, characterized by joint pain, tenderness, and functional disability. The percentage of Americans over 65 years of age is the fastest growing segment of the population, which is expected to reach 68 million people by the year 2010. A biochemical test for osteoarthritis would be particularly useful for early detection, assessment of disease severity and progression, and to monitor the effects of therapies.

Advances in the molecular biology, biochemistry, and metabolism of cartilage have stimulated the quest for appropriate markers of degradative and regenerative processes in osteoarthritis. Important new studies indicate

that molecular fragments of cartilage-derived matrix molecules are present in the blood and joint fluid in osteoarthritis that have the potential to represent disease-specific markers. The increased rates of cartilage degeneration increase the concentration of matrix components in tissue and body fluids, thus reflecting changes in the rates of cartilage catabolism. Further, cartilage degeneration in osteoarthritis changes the type or structure of the molecules being synthesized by the chondrocytes. Thus, the presence of these neo-epitopes may be a marker of degenerative events within the tissue. Markers of metabolic changes in subchondral bone or other joint tissues in osteoarthritis are also of potential interest. For examples of areas of interest, see NIAMS Topics.pdf.

Muscle Biology, Exercise Physiology and Sports Medicine

A. *Muscle Biology Branch*.
Supports research on skeletal muscle, its diseases and disorders, and its central role in human physiology and exercise. Topics include the molecular structure of muscle and the molecular mechanisms that produce force and motion. An aim is understanding the alterations in muscle resulting from increased exercise regimens and, conversely, the atrophy that follows immobilization during injury or illness. Some of the specific areas of research covered by the Muscle Biology Branch include Muscle Physiology, Molecular Architecture, Muscle Membranes, Muscle Development and Specialization, Musculoskeletal Fitness and Adaptive Biology, Muscle Diseases, and Sports Medicine, Muscle Injury and Muscle Repair. For examples of areas of interest, see NIAMS Topics.pdf.

Examples of more specific topics related to Muscle Biology, Exercise Physiology and Sports medicine may be found at:
http://www.nih.gov/niams/grants/ep4.htm

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Muscle Biology
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Skin Diseases
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NATIONAL CANCER INSTITUTE (NCI)

The NCI is the Federal Government's principal agency established to conduct and support cancer research, training, health information dissemination, and other related programs. As the effector of the National Cancer Program, the NCI supports a comprehensive approach to the problems of cancer through intensive investigation in the cause, diagnosis, prevention, early detection, treatment, rehabilitation from cancer, and the continuing care of cancer patients and families of cancer patients. To rapidly achieve the goal, NCI has developed a plan to: (1) sustain at full measure proven, productive research programs, (2) seize extraordinary scientific opportunities made possible by previous research discoveries, and (3) create and sustain mechanisms that build the capacity to allow the scientific community to apply rapidly evolving discoveries and emerging technologies for the benefit of human health.

Many of the topics below are “open-ended” to encourage submission of innovative SBIR/STTR projects that fit within the mission of NCI. For additional information about areas of interest to NCI, please visit our home page at http://www.nci.nih.gov. The NCI small business site http://www.cancer.gov/smallbusiness may also be of interest.

Division of Cancer Biology

The Division of Cancer Biology (DCB) plans and directs, coordinates, and evaluates a grant- and contract-supported program of extramural basic and applied research on cancer cell biology and cancer immunology, and cancer etiology, including the effects of biological, chemical and physical agents, in the promotion of cancer; maintains surveillance over developments in its program and assesses the national need for research in cancer biology, immunology and etiology; evaluates mechanisms of biological, chemical and physical carcinogenesis and subsequent tumor growth and progression to metastasis; tests for carcinogenic potential of environmental agents; serves as the focal point for the Federal Government on the synthesis of clinical, epidemiological and experimental data concerning biological agents relating to cancer; and maintains the necessary scientific management capability to foster and guide an effective research program. DCB supports grant research under the following seven branches/programs:

A. *Biological Carcinogenesis.* The Biological Carcinogenesis Branch (BCB) supports research that seeks to determine the role of microbiological agents as factors or cofactors in the etiology of human and animal cancer. The biological agents of primary interest are DNA viruses, RNA viruses, AIDS and AIDS-associated viruses, although the research may encompass all forms of life including bacteria and other microbial agents associated with cancer and use animal models of cancer and cancer vaccines. A wide range of approaches are supported, including basic biochemistry and molecular biology of oncogenic and suspected oncogenic agents, viral oncogenes and associated tumor suppressor genes, pathogenesis and natural history studies, animal models, and preventive vaccine research. The development of technologies to facilitate studies relating to biological carcinogenesis research is also encouraged. For examples of areas of interest, see NCI Topics.pdf.

B. *Cancer Cell Biology.* The Cancer Cell Biology Branch (CCBB) seeks to understand the biological basis of cancer at the cellular and molecular level. This research utilizes lower eukaryote and animal models, and animal and human tumor cells and tissues to analyze the mechanisms responsible for the growth and progression of cancer. For examples of areas of interest, see NCI Topics.pdf.

C. *Cancer Immunology and Hematology.* The Cancer Immunology and Hematology Branch (CIHB) supports a broad spectrum of basic research focused on the earliest stages of hematopoiesis and tracing the molecular events that lead to the development of all the functional elements of the immune system and, when errors occur, to the development of leukemias and lymphomas. Most research of interest falls into three major areas. The first is the immune response to tumors to include studies of all of the cells (T, B, NK, antigen-presenting, and other myeloid cells) and secreted molecules (antibodies and cytokines) of the immune system that can recognize and affect tumor growth. Emphasis is placed on the regulatory mechanisms responsible for the failure of immune response to eradicate most tumors under normal conditions, and the

development of strategies to circumvent these mechanisms. A second major area of interest examines the biology of hematopoietic malignancies to describe the detailed reasons underlying cell's failure to respond to normal growth controls and to develop novel approaches to prevention or therapy. The third distinct area supported is the basic biology of bone-marrow transplantation, including studies of host cell engraftment, graft-versus-host disease, and the basis of the graft-versus-leukemia effect. For examples of areas of interest, see NCI Topics.pdf.

D. *Chemical and Physical Carcinogenesis.* The Chemical and Physical Carcinogenesis Branch (CPCB) supports basic and applied research concerned with cancers caused or promoted by chemical or physical agents. Carcinogenesis research is supported at the molecular level in areas such as the genetics of cell transformation, mutagenesis, tumor promotion, and DNA damage. Mechanistic studies are encouraged in areas such as metabolism, toxicity and physiological distribution of carcinogens, genetics and regulation of enzymes, biochemical and molecular markers, and organ and cell culture systems and animal models. Also of interest are studies on cancer etiology by environmental chemicals, tobacco consumption and exposure, nutritional hazards, alcohol, asbestos, silica, and man-made fibers. CPCB supports studies on endogenous exposure to steroid hormones and the generation of oxygen radicals during normal metabolism, studies on phytoestrogens and xenoestrogens and their impact on the metabolism of endogenous estrogens are also supported, and work on carcinogenicity/mutagenicity, testing procedures and the development of analytical technologies for use in carcinogenesis research. For examples of areas of interest, see NCI Topics.pdf.

E. *DNA and Chromosome Aberrations*. The DNA and Chromosome Aberrations Branch (DCAB) seeks to study the genome at the DNA and chromosome level, including discovery of genes at sites of chromosome breaks, deletions, and translocations, DNA repair, structure and mechanisms of chromosome alterations, epigenetic changes, radiation- and chemical-induced changes in DNA replication and other alterations, and analytical technologies. For examples of areas of interest, see NCI Topics.pdf.

F. *Mouse Models of Human Cancers Consortium.* The Mouse Models of Human Cancer Consortium is a program based in the Office of the Director, DCB. The Consortium has the important goal of providing mouse cancer model-related resources and infrastructure to the research community, in part through various outreach activities. The outreach requirement generates the need for innovative educational or informational materials that convey the content of Consortium meetings and symposia, or document hands-on workshops in which models or techniques that are pertinent to mouse modeling are demonstrated. The instructional materials may be CD-ROMs, videotapes, Web-based interactive programs, or other media. For examples of areas of interest, see NCI Topics.pdf.

G. *Structural Biology and Molecular Applications*. The Structure Biology and Molecular Applications Branch (SBMAB) focuses on structural and molecular studies to explore the processes of carcinogenesis and tumorigenesis. Areas of interest include structural biology, genomics, proteomics, molecular and cellular imaging, enzymology, bio-related and combinatorial chemistry, and bioinformatics, as they apply to cancer biology. Interests also include modeling and theoretical approaches to cellular and molecular dimensions of cancer biology. For examples of areas of interest, see NCI Topics.pdf.

H. *Tumor Biology and Metastasis*. The Tumor Biology and Metastasis Branch (TBMB) supports research focused on the interaction of the tumor with its local environment, the mechanism of tumor cells' acquisition of aggressive malignant behavior, and the influence of hormonal factors on tumor progression. Special emphasis is given to the development of appropriate animal and cellular models of metastasis. Research in tumor biology includes studies on: (1) the role of cell adhesion molecules; (2) the role the extracellular matrix and the basement membrane in development, tissue morphogenesis, wound healing, invasion,

and metastasis; (3) the role of cytoskeleton, and nuclear matrix in cell proliferation, migration, and invasion; and (4) studies on gap junctional structures. Research in tumor progression and metastasis includes studies on: (1) the role of oncogenes and tumor suppressor genes in angiogenesis, matrix degradation, and metastasis; (2) the glycobiology of epithelial cell surfaces and functional consequences of aberrant glycosylation on cell adhesion, tumor progression, and metastasis; and (3) the role of steroid hormones and their receptors in transformation, tumor growth, and in the development of hormone independence during tumor progression. Models utilized in these studies may include animals, tumor tissues/cells, their components or their products. TBMB also focuses on the role of steroid hormones and their receptors during tumor growth and progression. For examples of areas of interest, see NCI Topics.pdf.

Division of Cancer Control and Population Sciences

The Division of Cancer Control and Population Sciences conducts basic and applied research in the behavioral, social, and population sciences, including epidemiology, biostatistics, and genetics that, independently or in combination with biomedical approaches, reduces cancer risk, incidence, morbidity, and mortality. Laboratory, clinical and population-based research, and health care are translated into cancer prevention, detection, treatment, and rehabilitation activities that cross the life span and the entire process of carcinogenesis, from primary behavioral prevention in youth, to screening, treatment, and survivorship. For additional information, please visit our home page at http://dccps.nci.nih.gov.

A. *Epidemiology and Genetics*. The Epidemiology and Genetics Program supports research in epidemiology, biometry, genetic epidemiology, molecular epidemiology, nutritional epidemiology, infectious epidemiology, environmental epidemiology, computing methodology, and multidisciplinary activities related to human cancers. For examples of areas of interest, see NCI Topics.pdf.

B. *Multimedia Technology and Health Communication in Cancer Control*. A major objective of DCCPS is to plan and conduct extramural, grant-supported programs of cancer prevention and control research in medical and community settings that focus on biomedical and behavioral factors that alter cancer risk. Toward this effort, the Multimedia Technology and Health Communication Program promotes innovative ways of translating cancer research into interventions, programs, systems, networks, or products needed by health care professionals or the public to reduce cancer risks, provide treatment options, or address the needs of cancer survivors.

Grant applicants are required to develop, implement, and test the effectiveness of new or existing models of behavior modification or informational/educational applications using computer applications, advanced telephone technologies, videos, cable and broadcast television, radio, virtual reality, animation, digital imaging, smart cards, the Internet or the World-Wide-Web. For examples of areas of interest, see NCI Topics.pdf.

Division of Cancer Treatment and Diagnosis

The Division of Cancer Treatment and Diagnosis (1) plans, directs and coordinates a program of extramural preclinical and clinical cancer treatment research as well as research conducted in cooperation with other Federal agencies with the objective of curing or controlling cancer in man by utilizing treatment modalities singly or in combination; (2) administers targeted research and development programs in the area of drug development, diagnosis, biological response modifiers, medical diagnostic imaging, and radiotherapy development; and (3) serves as the national focal point for information and data on experimental and clinical studies related to cancer treatment and for the distribution of such information to appropriate scientists and physicians; and (4) plans, directs and coordinates an extramural program of basic and applied research conducted at cancer centers and through the organ systems program. DCTD supports grant research under the following seven programs.

A. *Cancer Diagnosis*. The Cancer Diagnosis Program (CDP) supports the development of technologies, reagents, instrumentation,

and methodologies to improve cancer diagnosis or prognosis or to predict or assess response to therapy. This does not include technologies for imaging of patients. CDP also supports the adaptation or improvement of basic research technologies for use as clinical tools. Technologies supported by CDP may be designed to work with tissues, blood, serum, urine, or other biological fluids. For examples of areas of interest, see NCI Topics.pdf.

For additional information about areas of interest to the CDP Technology Development Branch, visit our home page at: http://www-cdp.ims.nci.nih.gov/tdb.html.

B. *Biochemistry and Pharmacology*. Preclinical studies designed to improve cancer treatment in the following areas: Discovery of new drugs and treatment strategies, selective targeting, development of new preclinical models, pharmaceutical development, and toxicologic evaluations. Emphasis is on molecular targeted approaches. For examples of areas of interest, see NCI Topics.pdf.

In addition to Biochemistry and Pharmacology sponsors special initiatives for Small Business Innovation Research (SBIR) and Small Technology Transfer Research (STTR) programs. For additional information, please visit our home page at http://dtp.nci.nih.gov/and select “Funding.”

C. *Cancer and Nutrition*. Research to improve the methodology of nutritional assessment in a cancer population. Innovative approaches to evaluate the contribution of nutritional status to response to cancer treatment.

D. *Clinical Treatment Research*. Clinical research studies designed to improve cancer treatment. Emphasis is on clinical trials for the evaluation of new therapeutic agents, development of assay systems to measure patient response to chemotherapy, development of prognostic assays, and development of methods of analysis and management of clinical trials data. For examples of areas of interest, see NCI Topics.pdf.

E. *Diagnostic and Medical Imaging Systems*. The development of imaging technology and in vivo imaging methods as required for research or clinical investigations using either pre-clinical models or human subjects. The research scope includes: (1) diagnostic imaging with ionizing or non-ionizing radiation and/or any other types of in vivo imaging technology or imaging methods; and (2) research related to the biological and health effects of diagnostic and/or combined diagnostic/therapeutic procedures. For examples of areas of interest, see NCI Topics.pdf.

F. *Radiation Research*. The Radiation Research Program (RRP) supports basic, developmental, and applied (clinical) research related to cancer treatment utilizing ionizing and non-ionizing radiations. Therapeutic modalities include photon therapy, particle therapy, photodynamic therapy (PDT), hyperthermia, radioimmunotherapy (RIT), and boron neutron capture therapy (BNCT). Radiation research encompasses a range of scientific disciplines including basic biology, chemistry, physics, and clinical radiation oncology. For examples of areas of interest, see NCI Topics.pdf.

G. *Biological Response Modifiers (BRM)*. Research on agents or approaches that alter the relationship between tumor and host by modifying the host's biological response to tumor cells with resultant therapeutic benefits. Both preclinical and clinical investigations are conducted on the utility of a wide variety of natural and synthetic agents and on biological manipulations of immunological and non-immunological host mediated, tumor-growth controlling mechanisms in cancer therapy. In addition, development of new approaches to modify host responses to the human immunodeficiency virus (HIV) is included in the scope of this announcement. Studies are encouraged which utilize in vitro assays and/or animal model systems to investigate mechanisms of BRMs. For examples of areas of interest, see NCI Topics.pdf.

Division of Cancer Prevention

The Division of Cancer Prevention (DCP) directs an extramural program of cancer prevention research including chemoprevention, nutritional science, genetic and infectious agent, early detection including biomarker development and validation and biometry.for the Institute. DCP also supports research training and career

development in cancer prevention and early detection and coordinates community-based clinical research in cancer prevention and dissemination of cancer treatment practice through a consortium of community clinical centers. For examples of areas of interest, see NCI Topics.pdf. For additional information, please visit our home page at http://dcp.nci.nih.gov.

A. *Prevention*. Research studies to identify, evaluate, and implement techniques and approaches for the prevention and early detection of cancer. Those studies capable of achieving these objectives with minimal risk and cost are preferred. For examples of areas of interest, see NCI Topics.pdf.

B. *Community Oncology*. Introduction, application, and evaluation of effective and practical cancer control intervention programs in community settings. Primary emphasis is on the integration and involvement of community physicians and allied health professionals in cancer control efforts and the promotion of linkages between community practitioners/hospitals and other regional resources for cancer control.

   Objectives are to: (1) reduce the time between research advances in prevention, detection, and patient management and their application in community settings; and (2) expand extend the cancer care knowledge and applications bases; and (3) evaluate new detection and diagnostic methods for specificity, sensitivity, reliability, validity, safety, feasibility and cost when applied to defined or target populations. This may include screening research as well.

C. *Rehabilitation and Continuing Care*. Development and evaluation of rehabilitation or continuing care strategies which directly enhance functioning of patients with cancer or which contribute to understanding of factors impacting utilization of supportive services by cancer patients. Clinical applications include development and testing of interventions to enhance multidisciplinary approaches to cancer rehabilitation, and research on effective symptom management (e.g., cancer-related pain, fatigue, nausea, mucositis). Areas of general program interest include innovative approaches to measuring and enhancing quality of life of cancer patients; research to investigate and enhance clinical decision-making by both patients and physicians; and studies of the impact of individual preferences for health care outcomes and their impact on cancer prevention practices in persons without cancer and on treatment decisions in patients with cancer.

D. *Early Detection and Screening*. New diagnostic or screening methods for early detection of cancer, especially for asymptomatic patients. Detection methods can include any cancer site, although there is more interest in the common cancers, such as those of the lung and colon. Methods should be cost beneficial and applicable in a clinical setting. For examples of areas of interest, see NCI Topics.pdf.

Other Research Topics Within the Mission of Institute

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Division of Cancer Biology

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Division of Cancer Control and Population Sciences

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For additional NCI-related SBIR Information, contact:

http://www.cancer.gov/smallbusiness

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

The NICHD conducts and supports research and research training on biological and behavioral aspects of human development. Primary program areas include: reproduction and population studies, pregnancy, perinatal biology, maternal and infant well-being, developmental and reproductive immunology, congenital defects, developmental biology, nutrition and growth, human learning and behavior, learning disabilities, cognitive and social development, mental retardation and developmental disabilities, AIDS and HIV, and medical rehabilitation.

For additional information about areas of interest to the NICHD, please visit our home page at http://www.nichd.nih.gov.

Population Research

Research on topics in reproductive sciences, contraceptive development, and demographic and behavioral sciences.

A. *Reproductive Sciences*. Research on the reproductive processes of men and women and of animals with similar reproductive systems related to developing safer and more effective means of regulating, preserving or achieving fertility. Particular areas of programmatic interest relative to small business initiatives include, but are not limited to:

Dr. Susan Taymans
(301) 496-6517; Fax: (301) 496-0962
Email: taymanss@mail.nih.gov

B. *Contraceptive and Reproductive Health Research.* Emphasis is on developing new and improved methods of fertility regulation, for men and for women, that are safe, effective, inexpensive, reversible, and acceptable; developing new and improved treatments for disorders of the male and female reproductive system, including those used for hormone therapy; discovery and dissemination of new knowledge concerning the medical benefits and risks of contraceptives and other drugs, devices, and surgical procedures as they affect reproductive health, primarily focusing on applied research involving epidemiology studies or Phase III/IV trials designed to detect clinically significant adverse effects, particularly those too rare to be determined through the premarketing approval process of the Food and Drug Administration. Laboratory models are utilized to further the understanding of mechanisms of action and to supplement epidemiologic and clinical observations; they are also used when human studies are not feasible.

Dr. Steven Kaufman
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Email: sk11p@nih.gov

C. *Demographic and Behavioral Sciences*. Research on the size, growth, and composition of populations and the impact of changes in population on the health and well-being of individuals, families, and the population itself. The program emphasizes not only factors affecting fertility, mortality, population movement and compositional change, but also teenage childbearing, AIDS, single-parent families, racial and ethnic differentials in infant mortality, legal, and undocumented immigration, and the well-being of children.

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For examples of areas of interest, see NICHD Topics.pdf.

Research for Mothers and Children

Research in seven major program areas:

A. *Pregnancy and Perinatology*. Research on the physiology of pregnancy and labor; high-risk pregnancies, including those with hypertensive disorders, diabetes or seizure disorders; fetal pathophysiology; premature labor and birth; disorders of the newborn; sudden infant death syndrome; and biological and behavioral antecedents of low birth weight.

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B. *Developmental Biology, Genetics, and Teratology*. Cellular, molecular, and genetic aspects of embryonic and fetal development and its aberrations, including early embryogenesis, limb formation, development of the nervous system, developmental and reproductive immunology, and teratology.

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C. *Endocrinology, Nutrition, and Growth*. Research on the nutritional needs of pregnant women and their fetuses; aspects of nutrients related to reproduction, growth and development; breast feeding and lactation; the immunology of breast milk; development of the gastrointestinal system; childhood obesity and the nutritional antecedents of adult disease; developmental endocrinology; and mechanism of hormone action during growth and development.

Dr. Gilman D. Grave
(301) 496-5593; Fax: (301) 480-9791
Email: gg37v@nih.gov

D. *Mental Retardation and Developmental Disabilities*. Biomedical research in neuroscience, genetics, biochemistry, molecular biology, and psychobiology

aimed at identifying factors that cause abnormal brain maturation and function; identification of direct and indirect social, economic and cultural influences on the occurrence of mental retardation and developmental disabilities (MRDD); and research leading to the assessment, prevention, and amelioration of MRDD, including screening and prenatal diagnosis.

Dr. Marie Bristol-Powers
(301) 402-1822; Fax: (301) 496-3791
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E. *Child Development and Behavior*. Research and research training programs in developmental psychology (cognitive, affective, and social development), cognitive psychology, cognitive neuroscience, language acquisition and bilingualism, developmental neuropsychology, and educational psychology; studies to define, classify, and map the developmental course of specific learning disabilities and disorders of attention; studies to elucidate the etiological role of cognitive, linguistic, perceptual, educational, genetic, social, and neurobiological mechanisms in dyslexia, learning disabilities, language disorders, and disorders of attention; investigations of the effects of well-defined treatment interventions on specific types of learning disabilities; studies designed to understand the development of attention, reasoning, planning, problem solving, and concept formation in children; studies delineating the effects of motivation, emotion, societal, cultural, familial, and neurobiological influences on social, emotional, and cognitive development; examinations of the effects of parental and non-parental care on social, emotional, and cognitive developmental outcomes; and investigations of temperament, motivation, self-concept, attitudes, and values, and their relationship to development.

Dr. Reid Lyon
(301) 496-9849; Fax: (301) 480-7773
Email: rl60a@nih.gov

F. *Pediatric, Adolescent, and Maternal AIDS*. Research on all aspects of HIV (human immunodeficiency virus) infection and disease, including AIDS in women of child-bearing age, pregnant women, mothers, fetuses, infants, children, and adolescents. Areas of interest include, but are not limited to, epidemiology, natural history, pathogenesis, treatment, and prevention.

Dr. Robert Nugent
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Email: rn22e@nih.gov

Medical Rehabilitation Research

Research is encouraged on the restoration, replacement, or enhancement of functioning required by children or adults with physical disabilities to be effective in daily life. . Emphasis is on improving functional mobility, promoting behavioral adaptation to functional losses, assessing the efficacy and outcomes of medical rehabilitation therapies and practices; developing improved assistive technology; understanding whole body system responses to physical impairments and functional changes; developing more precise methods to measure impairments, disabilities, and societal limitations; and training health professionals in the field of medical rehabilitation. For examples of areas of interest, see NICHD Topics.pdf.

Dr. Louis A. Quatrano
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Other Research Topic(s) Within Mission of Institute

For additional information on research topics, contact:

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For administrative and business management questions, contact:

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Email: dw40j@nih.gov

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

The mission of the NIDA is to lead the nation in bringing the power of science to bear on drug abuse and addiction, through support and conduct of research across a broad range of disciplines and by ensuring rapid and effective dissemination and use of research results to improve prevention, treatment, and policy. For additional information about areas of interest to the NIDA, please visit our home page at http://www.nida.nih.gov/.

Division of Treatment Research and Development

The NIDA DTR&D supports research aimed at the development and testing of pharmacological and behavioral treatments for drug abuse and addiction. This includes the identification, evaluation, development, approvability, and efficacy testing of new and improved pharmacotherapeutic agents, as well as the testing of marketed medications, and of behavioral treatments used alone or integrated with medications. The DTR&D also advances a human neuroscience research and training program focused on understanding the neurobiological substrates of drug abuse and addiction processes.

A. *Chemistry and Pharmaceutics Branch (CPB)*

The CPB supports research in the design (including molecular modeling and structure-activity relationship studies) and synthesis of novel compounds, formulation development, bioanalytical methods development, and pharmacokinetics/ pharmacodynamics aimed at the discovery and development of new medications for treating drug addiction. (NIDA-CPB). For examples of areas of interest, see NIDA Topics.pdf.

1. ***Research Related to the Design and Development of New Compounds and Improved Drug Products (Drug Delivery) for the Treatment of Drug Addiction***

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Email: jb168r@nih.gov

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(301) 443-8293
Email: rk108@nih.gov

Nora Chiang, Ph.D.
(301) 443-8099
Email: nc34b@nih.gov

Moo Park, Ph.D.
(301) 443-5280
Email: mp264a@nih.gov

B. *Medications Discovery and Toxicology Branch (MDTB)*

The MDTB supports research on the development of preclinical behavioral models (e.g., of craving, drug-seeking behavior, dependence, or relapse), biochemical assays, gene expressional assays and electrophysiological methods to identify and characterize new medications to treat substance abuse, as well as pharmacological screening of novel compounds to identify potential drug abuse medications. The Branch also supports research on toxicity studies of potential medications for the treatment of substance abuse, and interactions of potential treatment medications with abused substances. For examples of areas of interest, see NIDA Topics.pdf.

1. ***Development of New Methods for Discovery of Medications Useful in Treating Drug Addiction***

David J. McCann, Ph.D.
(301) 443-2999
Email: dm102t@nih.gov

2. ***Development of Methods to Detect Adverse Cardiovascular Interactions Between Cocaine and Potential Cocaine Dependence Treatment Medications***

James B. Terrill, Ph.D.
(301) 443-8289
Email: jt62r@nih.gov

C. *Behavioral Treatment Development Branch (BTDB)*

The BTDB supports research on behavioral treatments and combined behavioral and pharmacological treatments. Behavioral treatments include psychotherapies, behavior therapies, family therapies, group therapies, counseling strategies,

rehabilitative techniques, brief behavioral interventions, therapeutic community treatments, and other psychosocial treatments. Research on these treatments may be carried out in any setting, including both academic and community or "real-world" settings. For examples of areas of interest, see NIDA Topics.pdf.

1. ***Behavioral Strategies for Increasing Compliance in Taking Treatment Medication***
2. ***Integration of Behavioral Therapies and Pharmacotherapies***
3. ***Drug Abuse Treatment in Primary Care Settings***
4. ***Woman and Gender Differences in the Provision of Behavioral Treatments, and HIV/AIDS Risk Reduction Approaches***
5. ***Transporting Behavioral Treatments to Community Practitioners***
6. ***Using Telemedicine to Disseminate Drug Addiction Research Findings to Primary Health Care Providers***
7. ***Developing Culturally Sensitive Behavioral Therapies for Racial and Ethnic Minorities***

Dorynne Czechowicz, M.D.
(301) 443-0107
Email: dc97d@nih.gov

8. ***Behavioral Therapy Development***
9. ***Innovative Technologies for Drug Abuse Treatment and HIV Risk Reduction***
10. ***Development of HIV Risk Reduction Intervention***
11. ***Alternative and/or Complementary (A/C) Interventions for Drug Abuse Treatment***
12. ***Development of New or Improved Addiction Assessment Measures and Procedures***
13. ***Behavioral Therapies for Pre-Adolescents and Adolescents***

D. *Clinical Neurobiology Branch (CNB)*

The CNB supports research on the clinical neurobiology of addiction (exploring alterations of the structure and/or function of the human central nervous system following acute or chronic exposure of drugs of abuse), and the neurobiology of development (neurobiological effects of drugs of abuse and addiction during various stages of development and maturation, effects of drug exposure on neurobiological processes, development of methodologies and refinement of techniques used in pediatric neuroimaging). The Branch also supports cognitive neuroscience of drug abuse and addiction, and the neurobiology of treatment, HIV/AIDS, and human pain and analgesia. For examples of areas of interest, see NIDA Topics.pdf.

1. ***Development of Novel Approaches in Human Neuroscience***

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301-402-1746
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Debra Grossman, M.S.
301-443-0107
E-mail: dg79a@nih.gov

Steven Grant, Ph.D.
(301) 443-4877
Email: sg103h@nih.gov

E. *Medications Research Grants Branch (MRGB)*

The MRGB supports research on controlled clinical pharmacological studies to assess a compound's potential as a drug abuse treatment medications, controlled clinical trials for the development or new agents for treatment, or complications of drug abuse (withdrawal, relapse, overdose).

Division of Basic Neuroscience and Behavioral Research (DNBR)

DNBR's basic neuroscience and behavioral research focuses on understanding the mechanisms, characteristics, and processes of drug abuse. Basic behavioral, cognitive, neurobiological, cellular, molecular, chemical, and genetics research aims at characterizing and understanding drug seeking, compulsive behavior, and addictive processes. These

research areas necessarily include studies of normal processes.

Using both animal and human studies, basic behavioral research focuses on behavioral and cognitive processes that may or do lead to drug initiation, and the behavioral and cognitive consequences of drug abuse. Neurobiology research focuses on the neural mechanisms and substrates underlying behavioral and cognitive processes and vulnerability factors associated with drug abuse, addiction, sensitization, tolerance, and relapse.

DNBR supports basic chemistry and pharmacological studies focusing on structure/activity relationships, definition, and characterization of systems involved in drug actions, chemical synthesis of new ligands, pharmacokinetics, analytical methods, understanding basic mechanisms of drug action and drug testing.

Computational and theoretical modeling of biological systems and behavioral processes, biomedical computing and/or information science and technology development is supported by DNBR. For examples of areas of interest, see NIDA Topics.pdf.

1. ***Research Related to the Design of New Therapeutic Approaches***

Thomas G. Aigner, Ph.D.
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Email: ta17r@nih.gov

2. ***Virtual Reality for Treatment of Pain***
3. ***Virtual Reality for the Treatment of Drug Abuse***

David Thomas, Ph.D.
301-443-6975
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4. ***Development of innovative probes and research products/dosage forms for drug abuse/addiction research***
5. ***Chemical Libraries for Drug Development***
6. ***Analytical Techniques***

Hari H. Singh, Ph.D.
(301) 443-6300
Email: hs87j@nih.gov

7. ***Conantokins***

Paul Hillery, Ph.D.
(301)-443-6275
Email: ph44x@nih.gov

8. ***Genetic Studies***

Jonathan Pollock, Ph.D.
(301) 443-6300
Email: jp183r@nih.gov

9. ***Drug Testing Development***

Beth Babecki, M.A.
(301) 443-1887
Email: mb128t@nih.gov

10. ***Biotechnology***

Paul Hillery, Ph.D.
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11. ***Effects of Drugs at the Cellular Level***

Jonathan Pollock, Ph.D.
(301) 443-6300
Email: jp183r@nih.gov

12. Toxicity Studies

Pushpa V. Thadani, Ph.D.
(301) 443-6300
Email: pt24e@nih.gov

13. ***Development of Diagnostic Tools that are Predictive of Cardiovascular Complications Associated with Crack/Cocaine Use***

Pushpa V. Thadani, Ph.D.
(301) 443-6300
Email: pt24e@nih.gov

14. ***Predisposition to Cardiovascular Complications Associated with Abused Substance(s)***

Pushpa V. Thadani, Ph.D.
(301) 443-6300
Email: pt24e@nih.gov

14. ***Opioid Peptides***
15. ***Dopamine and Serotonin Receptor Ligands***

Rao Rapaka, Ph.D.
(301) 443-6300
Email: rr82u@nih.gov

Office of Science Policy and Communications (OSPC)

A. *Science Policy Branch (SPB)*

1. ***Science Education.*** For examples of areas of interest, see NIDA Topics.pdf.

Cathrine A. Sasek, Ph.D.
(301) 443-6071
Email: csasek@nih.gov

Division of Epidemiology Services and Prevention Research (DESPR)

A. *Prevention Research Branch (PRB).*

The Prevention Research Branch (PRB) supports a program of research in drug abuse and drug related HIV prevention to (a) examine the efficacy and effectiveness of new and innovative theory-based prevention approaches, (b) determine the components of research-based intervention strategies and programs that account for effectiveness of approaches, (c) clarify organizational, management, and delivery factors related to the effective and efficient provision of prevention services, and (d) develop and test methodologies appropriate for studying these complex aspects of prevention science.

1. ***Prevention Research.*** Prevention research is encouraged to conduct rigorous scientific study of multiple component substance abuse prevention technologies to be implemented through multiple levels of the social environment including: the family, schools, peer groups and organizations, the workplace, health care systems, etc. The purpose of this research is to determine the efficacy and effectiveness of programming or technologies in preventing the onset of drug use and progression to abuse and addiction. Technologies should entail a comprehensive approach at the universal, selective, and/or indicated levels. Universal prevention interventions target the general public or a whole population group. Selective prevention interventions target individuals or a subgroup of the population with defined risk factors for substance abuse. Indicated preventive interventions target individuals or subgroups who are identified as having detectable signs or symptoms foreshadowing drug abuse and addiction and who have not met diagnostic criteria. NIDA encourages the development and testing of innovative prevention intervention technologies that are sensitive and relevant to cultural and gender differences. These technologies may include, but need not be limited to, the Internet, CD-ROM programs, test materials and videos, as well as tele-training via satellite, computer-assisted instruction, and virtual reality. For examples of areas of interest, see NIDA Topics.pdf.

Larry A. Seitz, Ph.D.
(301) 402-1725
Email: ls75t@nih.gov

B. *Epidemiology Research Branch (ERB)*

The Epidemiology Research Branch (ERB) supports an extramural program for epidemiologic research concerning drug abuse which includes (a) incidence and prevalence of drug abuse (in various stages) and related conditions such as HIV/AIDS among general and specific subpopulations, (b) identification and study of resiliency and risk factors associated with drug abuse and related conditions, (c) etiologic studies on the origins and pathways of drug use during various stages of human development, (d) methodological studies designed to measure and improve the accuracy, collection, and reporting of data on drug abuse and related conditions, (e) development of innovative statistical approaches and research designs leading toward improved analysis of drug abuse characteristics, (f) international epidemiologic studies on drug use patterns, etiologic factors, and related concerns in various national and regional contexts.For examples of areas of interest, see NIDA Topics.pdf.

1. ***Assessment and Improvement of the Validity of Sensitive Data Collected in Drug Use Surveys***
2. ***Micodata Disclosure Analysis***
3. ***Development of Standardized Instruments for Measuring Illicit Drug Use, Abuse, and Dependence***

James Colliver, Ph.D.
(301) 443-6637
Email: jc186b@nih.gov

C. *Community Research Branch*

The Community Research Branch (CRB) supports research that focuses on the epidemiology, etiology, and prevention of adverse behavioral and social consequences associated with drug abuse which includes research to (a) identify, describe, and estimate the prevalence and incidence of adverse effects associated with drug abuse, (b) investigate the antecedents and determinants of adverse outcomes associated with drug abuse, (c) explore the role of emerging patterns of drug abuse on adverse behavioral and social outcomes (e.g., education attainment, violence, poverty) as well as the role of adverse outcomes on further drug involvement, and (d) develop, implement, and evaluate prevention interventions to mitigate or contribute to adverse consequences of drug abuse. For examples of areas of interest, see NIDA Topics.pdf.

1. ***Instrument Development for Assessing Community Factors that Affect Drug Use and its Consequences***

Jacques Normand, Ph.D.
(301) 443-4060
Email: jn86a@nih.gov

D. *Services Research Branch (SRB)*

The Services Research Branch (SRB) supports a program of research on the effectiveness of drug abuse treatment with a focus on the quality, cost, access to, and cost-effectiveness of care for drug abuse dependence disorders. Primary research foci include: (1) the effectiveness and cost-benefits and cost-effectiveness of drug abuse treatment, (2) factors affecting treatment access, utilization, and health and behavioral outcomes for defined populations, (3) the effects of organization, financing, and management of services on treatment outcomes, (4) drug abuse service delivery systems and models, such as continuity of care, stages of change, or service linkage and integration models, and (5) drug abuse treatment services for HIV seropositive patients and for those at risk of infection. For examples of areas of interest, see NIDA Topics.pdf.

1. ***Clinical Staff Management and Development Strategies***

Bennett Fletcher, Ph.D.
(301) 443-2274
Email: bf31v@nih.gov

2. ***Drug Abuse Treatment Economic Research***

William S. Cartwright, Ph.D.
(301) 443-4060
Email: wc34b@nih.gov

3. ***Personnel Selection Technology Research for Drug Abuse Treatment Clinics***
4. ***Customer Retention Technology***
5. ***Effective Management And Operation of Drug Abuse Treatment Services Delivery***

Thomas F. Hilton, Ph.D.
(301) 435-0808
Email: Tom.Hilton@nih.gov

6. ***Web-Based Technologies: Transporting Services Research to Practice***

Jerry Flanzer, DSW
(301) 443-4060
Email: jflanzer@nih.gov

Center on AIDS and Other Medical Consequences of Drug Abuse (CAMCODA)

The Center on AIDS and Other Medical Consequences of Drug Abuse (CAMCODA) develops and administers a national and international program of research on HIV/AIDS and other medical/health, mental health, and developmental consequences of drug abuse. CAMCODA also coordinates research activities, and collaborates with other NIDA components, on issues concerning HIV/AIDS and consequences of drug abuse. For examples of areas of interest, see NIDA Topics.pdf.

Vincent Smeriglio, Ph.D.
(301) 443-1801
Email: vs24o@nih.gov

1. ***Develop Improved Technology for Assessment of Prenatal Drug Exposure and Passive Postnatal Drug Exposure***

2. ***Develop Interactive Database Systems on Human Subjects Issues for Use by Drug Abuse Researchers Studying School-Age Children and Adolescents Drug Use***

3. ***Develop Improved Methods of Neuroimaging to Assess Structural and Functional Status of the Brains of Children and Adolescents Exposed to Drugs***

Vincent Smeriglio, Ph.D. or Katherine Davenny
(301) 443-1801
Email: vs24o@nih.govor kd25h@nih.gov

Other Research Topics Within the Mission of the Institute

NIDA encourages applications in other areas of research that may not be listed.

For additional information contact:

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National Institute on Drug Abuse
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For administrative and business management questions, contact:

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NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS (NIDCD)

The NIDCD supports research on the normal mechanisms of, as well as on diseases and disorders of hearing, balance, smell, taste, voice, speech and language. The Institute also supports research related to disease prevention and health promotion. The NIDCD addresses special biomedical and behavioral problems associated with people who have communication impairments or disorders. The NIDCD also supports efforts to create and refine devices that substitute for lost and impaired sensory and communication functions. For more specific information about areas of interest to the NIDCD, please visit our home page at http://www.nih.gov/nidcd/funding/grants/sbir.htm.

Hearing Program

Research and development related to hearing aids, cochlear implants, and other assistive devices (e.g., systems designed to improve access to and to increase utilization of computer and other information technologies, telecommunication devices, alerting systems) for individuals with hearing impairments; development of tests and instruments (including DNA-based assays) for the screening and diagnosis of hearing impairment, especially in neonates and infants; development of treatment modalities to prevent or lessen the effects of hearing disorders; development of new outcome measures for assessing the efficacy of treatments of hearing disorders; development of new research tools to aid in the study of the auditory system (e.g., imaging techniques, neuroanatomic tracers, electrophysiologic technology, new animal models); development of viral and non-viral vectors to enable gene transfer to the inner ear; and development of cell type specific probes to examine cell lineage in inner ear regeneration.

Lynn E. Luethke, Ph.D.
National Institute on Deafness and Other Communication Disorders
(301) 402-3458; Fax: (301) 402-6251
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Balance/Vestibular Program

Research to develop and refine tests of balance and vestibular function. Balance disorders affect a large proportion of the population, particularly the elderly. The vestibular system, with its receptor organs located in the inner ear, plays an important role in the maintenance of one's orientation in space, the control of balance while the body is immobile and in motion, and visual fixation of objects during head movement. Emphasis is on research and development of treatments for balance disorders; development of neuroimaging techniques and biochemical markers of disease in the vestibular system; development of systems to assess balance/vestibular function and for assessing the efficacy of physical rehabilitative regimens

for balance disorders; development of drug delivery systems targeting peptinergic molecules in the peripheral vestibular apparatus and the central vestibular circuits for the pharmacologic management of balance disorders; development of a comprehensive software system to assess eye movements associated with the vestibulo-ocular reflex; development of instrumentation and a clinical test protocol for assessing the vestibulo-ocular reflex during locomotion; development of instruments and tests for assessing otolithic function; development of instruments and tests measuring head stability during natural stimulation of the vestibular system; development of perceptual reporting techniques and psychological indices for the clinical assessment of the balance-disordered patient; development of new outcome measures for assessing the efficacy of physical rehabilitative regimens for balance disorders; and development of assistive devices for balance disorders.

Daniel Sklare, Ph.D.
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(301) 496-1804; Fax: (301) 402-6251
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Voice, Speech, and Language Programs

Research on studies of voice and speech disorders focus on determining the nature, causes, treatment and prevention of disorders such as stuttering, spasmodic dysphonia, and dysarthria. Emphasis is on research and development of diagnostic measures and intervention strategies for voice, speech, swallowing, and language disorders; development of communication and other assistive devices for individuals with voice, speech, swallowing, and language disorders; identification and development of computer and animal models for research in communication disorders; development of new systems for visual communication by individuals who are deaf or severely hearing impaired; development of new systems of communication for individuals with motor impairment; design and development of diagnostic measures or materials for early identification of speech and language impairment in children; development of tests for the assessment of childhood and adult language impairment in multi-cultural populations; development of assessment measures of sign language abilities; development of improved artificial larynges and tracheoesophageal shunts; development of artificial intelligence computer models that simulate normal and disordered speech and language.

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Smell and Taste Program

Research on the study the chemical senses of smell and taste to enhance understanding of how individuals communicate with their environment. Improved understanding of the interaction between chemoreception and food consumption will lead to improved nutrition from birth to old age. Both the olfactory and gustatory systems offer special approaches for understanding fundamental mechanisms of plasticity. Advances in molecular and cellular biology, biophysics, and biochemistry of the olfactory and gustatory systems are paving the way for improved diagnosis, prevention, and treatment of chemosensory disorders. Emphasis is on research and development of diagnostic tools for testing human smell and taste function; intervention strategies for smell and taste disorders; biosensors, electronic noses, and other assistive devices for chemosensory impairments; innovative approaches for obtaining functional expression of mammalian odorant receptors in heterologous cells and for assessing ligand-receptor specificities; development of a chemicals resource for providing chemicals at high purity for chemosensory research; development of a non-invasive drug delivery system using the primary olfactory nerve to target drugs to the central nervous system; development of model systems using stem cell populations from the olfactory and taste sensory organs for the study of neurogenesis; development of readily administered chemosensory tests for population studies; and development of tests to differentiate trigeminal from olfactory and gustatory stimulation.

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Other Research Topic(s) Within Mission of Institute

For additional information on research topics, contact:

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National Institute on Deafness and Other Communication Disorders
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For administrative and business management questions, contact:

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NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH (NIDCR)

The NIDR conducts and fosters research on the etiology, pathogenesis, prevention, diagnosis, and treatment of oral, craniofacial and dental diseases and conditions. For more specific information about areas of interest to the NIDR, please visit our home page at http://www.nidcr.nih.gov.

Inherited Diseases and Disorders

Emphasis is on etiology, prevention, and treatment of craniofacial anomalies such as cleft lip and palate, hemifacial microsomia, malocclusion, and syndromic and non-syndromic disorders that manifest craniofacial defects. This includes inherited and sporadic birth defects as well as acquired disfigurement and their effects on functions of the craniofacial region. For examples of areas of interest, see NIDCR Topics.pdf.

Infectious Diseases

Research relating to the etiology, pathogenesis, prevention, diagnosis and treatment of infectious diseases of the oral cavity is supported by the NIDCR. This includes research on practical ways to effectively use the host immune system to prevent or treat oral infectious diseases and microbial-induced inflammation. Infectious diseases of the oral cavity include caries, periodontitis, candidiasis, peri-implantitis, pulpitis, and various viral and fungal infections of the oral mucosa and research on the diagnosis and prevention of oral manifestations of HIV infection and AIDS. For examples of areas of interest, see NIDCR Topics.pdf.

Neoplastic Diseases

Emphasis is on the prevention, etiology, initiation, early detection, progression and treatment of pre-malignant and malignant oral lesions as well as the invasion and metastasis of oral cancer cells. For examples of areas of interest, see NIDCR Topics.pdf.

Chronic Disabling Diseases

Emphasis on research on chronic disabling diseases, including injury, of the oral-cranio facial-dental areas including neuropathies and neurodegenerative disorders, osteoporosis and other diseases of bone and connective tissue, diseases of the temporomandibular joint, autoimmune diseases (e.g., Sjogren's syndrome) which influence and which are influenced by diseases of the oral cavity, and reciprocal influences of other systemic diseases such as diabetes and cardiovascular diseases and the oral cavity. For examples of areas of interest, see NIDCR Topics.pdf.

Biomaterials, Biomimetics, and Tissue Engineering

Emphasis is on the development of natural and synthetic materials to be used for the repair, regeneration, restoration and reconstruction of oral tissues and organs; on the development and improvement of evaluation and measurement systems for the characterization of implanted material properties; on their interactions as well as on their performance under the severity of the biological environment; and finally on the development and/or improvement of new alloy combinations, especially those that are mercury free. For examples of areas of interest, see NIDCR Topics.pdf.

Behavior, Health Promotion and Environment

Research on patterns and outcomes of acute and chronic oral diseases, and on oral and systemic disease co-morbidities within the

population; socio-environmental or behavioral factors which influence host response, individual behaviors, care providers' behaviors, clinical decision making, information transfer technologies, dental utilization, health care delivery, treatment or health care outcomes and research which integrates biological or molecular determinants of health with sociobehavioral determinants. For examples of areas of interest, see NIDCR Topics.pdf.

Other Research Topic(s) Within Mission of Institute

For additional information on research topics, contact:

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NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

The NIDDK supports research in diabetes, endocrinology and metabolic diseases; digestive diseases and nutrition; and kidney, urologic and hematologic diseases. For additional information about areas of interest to the NIDDK, please visit our home page at http://www.niddk.nih.gov.

Diabetes, Endocrinology and Metabolic Diseases

The Division of Diabetes, Endocrinology and Metabolic Diseases supports basic and clinical research on the etiology, pathogenesis, prevention, diagnosis, and treatment of diabetes mellitus and its complications; endocrine diseases; osteoporosis; cystic fibrosis, and other metabolic disorders; as well as research on basic endocrine and metabolic processes. For examples of areas of interest, see NIDDK Topics.pdf.

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Digestive Diseases and Nutrition

The Division of Digestive Diseases and Nutrition supports research on the function, diseases and disorders of the digestive tract; the esophagus, stomach, intestine, colon, anorectum, pancreas, liver, gallbladder, and biliary tract; basic, clinical and behavioral research on nutrition and obesity as well as information transfer in the field of digestive diseases and prevention of obesity. Innovative investigator-initiated projects that are not mentioned below are encouraged. For examples of areas of interest, see NIDDK Topics.pdf.

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Kidney, Urologic and Hematologic Diseases

The Division of Kidney, Urologic, and Hematologic Diseases supports research into basic mechanisms of organ and tissue function and into the diseases of the kidney, urologic and hematologic systems. Projects to help develop an understanding of the physiology, pathophysiology, and related diseases of the kidney, urinary tract, and blood and blood forming systems so that rational treatments and means of prevention and/or arrest of diseases may be devised. Support for advances in the technology of cell and molecular biology that will enhance research in kidney, urologic and hematologic diseases is encouraged. For examples of areas of interest, see NIDDK Topics.pdf.

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Other Research Topic(s) Within Mission of Institute

For administrative and business management questions, contact:

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NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

Human health and human disease result from three interactive elements: environmental factors, genetic susceptibility and age. The mission of the NIEHS is to reduce the burden of human illness and dysfunction from environmental causes by further understanding each of these components and how they interrelate. NIEHS achieves its mission through a multidisciplinary biomedical research program, prevention and intervention efforts, and a communication strategy that encompasses training, education, technology transfer and community outreach. The ultimate goal of the NIEHS activities is to define and understand the mechanism of action of environmental agents on human health and to transfer this knowledge to the public benefit. Thus, as a part of this mission, NIEHS supports research and training focused on the identification, assessment and mechanism of action of agents in the environment that are potentially harmful to human health. Areas of emphasis:

A. Development and validation of alternative designs/methods for toxicity testing assessment.

B. Development of products/devices for measuring exposure to toxic agents.

C. Development and validation of bioengineering technology (including nanotechnology) for use in environmental health sciences.

D. Development of animal models that mimic the human disease process.

E. Development of educational materials related to Environmental Health Sciences.

F. Additional products related to the NIEHS mission of protecting/improving the public health by reducing the risk of toxicity due to exposure to environmental agents.

For examples of areas of interest, see NIEHS Topics.pdf.

For additional information about areas of interest to NIEHS, visit our home page at http://www.niehs.nih.gov.

Other Research Topic(s) Within Mission of Institute

For additional information on research topics, contact:

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NATIONAL EYE INSTITUTE (NEI)

The NEI supports research with respect to blinding eye diseases, visual disorders, mechanisms of normal visual function, preservation of sight, and the special health problems and requirements of individuals with impaired vision. The NEI's programs are described in extensive detail in documents which are available from the Institute.

For additional information about the research programs of the NEI, please visit our home page at http://www.nei.nih.gov.

Retinal Diseases Program

Research and development of new therapeutic approaches for ocular inflammatory diseases and to inhibit abnormal proliferation of the retinal and choroidal blood vessels; development of better methods of diagnosing and treating diabetic retinopathy and other vascular diseases of the retina and choroid; development of non-invasive techniques for early diagnosis of macular degeneration and other retinal degenerative diseases; development of instruments and procedures for improved surgical management of retinal detachments.

Corneal Diseases Program

Research and development of new therapeutic agents for the treatment of corneal diseases; development of innovative methods of drug delivery for ocular surface disorders; development of new biomaterials for corneal prostheses; development of instruments and procedures for correcting the refractive power of the cornea and measuring the cornea's optical and physiological properties.

Lens and Cataract Program

Research and development of therapeutic agents for the prevention of cataract; development of new approaches in the post-operative management of cataract surgery; development of new surgical instruments for cataract extraction and biomaterials for replacement of the natural lens.

Glaucoma Program

Research and development of new therapeutic agents, instruments, and procedures for the diagnosis and treatment of glaucoma; development of devices to aid patient's compliance with therapeutic regimens; development of non-invasive methods to measure damage to optic nerve head.

Strabismus, Amblyopia, and Visual Processing Program

Research into the identification and characterization of growth factors which facilitate regeneration of visual nerve axons; development of innovative techniques to study factors that facilitate regeneration and guidance of developing or regenerating nerve fibers; development of new approaches using imaging techniques, such as PET and MRI, to localize lesions and test the functioning of specific parts of the visual system, especially those involved in higher order visual processing.

Visual Impairment and Its Rehabilitation Program

Research and development of instruments and methods to better specify, measure, and categorize residual visual function; development and evaluation of optical, electronic, and other devices that meet the rehabilitative needs of persons who are blind or have low vision.

Other Research Topic(s) Within Mission of Institute

For additional information on research topics, contact:

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For administrative and business management questions, contact:

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Email:wd8u@nih.gov

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

The NIGMS supports research and research training in the basic medical sciences and related natural and behavioral sciences and in

specific clinical areas (i.e., clinical pharmacology, trauma and burn injury, and anesthesiology). The NIGMS also supports health-related research that is otherwise not assigned to another of the PHS components.

For additional information about areas of interest to the NIGMS, please visit our home page at http://www.nigms.nih.gov. This site includes staff contact information by program area (http://www.nigms.nih.gov/nigms_staff/contact.html) It also includes links to program announcements that highlight NIGMS areas of special emphasis (http://www.nigms.nih.gov/funding/funding.html). In some cases, these announcements specifically mention the SBIR and STTR grant mechanisms, in most cases they do not. However, it is clear that small businesses could make contributions to the research objectives described in these announcements.

Division of Cell Biology and Biophysics

Research on membrane synthesis, structure, and function; membrane models; membrane transport; cell division; cell organization; cell motility; and biophysics of proteins, nucleic acids, and biological assemblies, as well as the development of instrumentation, components, and methods for the analysis of cellular components and macromolecules by imaging, spectroscopy, and diffraction analysis.

SBIR and STTR proposals on the application of cell biology, biophysics, biochemistry, physics, mathematics, engineering, and chemistry to biomedical problems, and the development of instrumentation to facilitate research in cell biology and biophysics. For examples of areas of interest, see NIGMS Topics.pdf.

James Cassatt, Ph.D.
National Institute of General Medical Sciences
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Division of Genetics and Developmental Biology

Research on developing a better understanding of fundamental processes and mechanisms of development and inheritance in health and disease. Support of basic topics in genetics and developmental biology, including nucleic acid chemistry, the structure of genetic material, the mechanisms of transmission and expression of genetic information, cellular regulation of growth and differentiation, molecular immunology, and population genetics. For examples of areas of interest, see NIGMS Topics.pdf.

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Division of Pharmacology, Physiology, and Biological Chemistry

Research related to the actions of therapeutics, including anesthetics, and the development of biotechnological methods for their production and investigation. Research on pain management as it relates to anesthesia and the perioperative period. Research on responses to traumatic injury, including burn injury, and methods to mitigate these responses. Research leading to new knowledge of physiological functions at the molecular, cellular, and organ systems levels. Research on the structure, function, and biosynthesis of cellular components and cellular metabolism, bioenergetics, and mechanisms of enzyme action, regulation, and inhibition. Research leading to the synthesis of new materials or development of new chemical methods to probe biological phenomena or to alter the behavior of biological systems. For examples of areas of interest, see NIGMS Topics.pdf.

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Other Research Topic(s) Within Mission of Institute

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NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

The NHLBI plans, conducts and supports research, clinical trials and demonstrations

relating to the causes, prevention, diagnosis and treatment of heart, blood vessel, lung, and blood diseases and sleep disorders. The NHLBI SBIR/STTR program fosters basic, applied, and clinical research on all product and service development related to the mission of the NHLBI. Research may be targeted to gender, race, or age subgroups.

For more specific information about areas of interest to the NHLBI, please visit our home page at http://www.nhlbi.nih.gov.

Heart and Vascular Diseases

The Division of Heart and Vascular Diseases plans and directs the NHLBI's research grant, contract, and training programs in heart and vascular diseases. These programs encompass institute- and investigator-initiated basic research, targeted research, specialized centers and clinical trials. The DHVD maintains surveillance over developments in its program areas and assesses the national need for research on the causes, prevention, diagnosis, and treatment of cardiovascular disease. The DHVD ensures that effective new techniques, treatments and strategies resulting from medical research are transferred to the community through professional, patient, and public education programs in a timely manner.

The Division has three major programs: the Heart Research Program, the Vascular Biology Research Program, and the Clinical & Molecular Medicine Program, in addition to a Research Training and Special Programs Group.

Heart Research Program. Supports basic, applied, and clinical research in cardiac diseases, from embryonic life to adulthood.

Vascular Biology Research Program. Supports research in atherosclerosis, hypertension, basic vascular biology and gene therapy for the prevention and/or treatment of vascular diseases.

Clinical & Molecular Medicine Program. Supports clinical, basic and engineering research on cardiovascular disease and health. Its scope includes genetic, genomic and proteomic research; engineering theory and practice applied to biology and medicine including therapeutic cardiovascular devices and diagnostic instrumentation; informatics and simulation; and cohort, case-control, and randomized clinical trials.

For examples of areas of interest, see NHLBI Topics.pdf.

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Lung Diseases

The NHLBI Division of Lung Diseases (DLD) maintains surveillance over developments in pulmonary research and assesses the Nation's need for research on the causes, prevention, diagnosis, and treatment of pulmonary diseases. Also within the purview of the Division are: technology development, application of research findings, and research training and career development in pulmonary diseases. The DLD plans and directs the research and training programs which encompass basic research, applied research and development, clinical investigations, clinical trials, and demonstration and education research. Two programs comprise the Division of Lung Diseases: the Airway Biology and Disease Program, and the Lung Biology and Disease Program.

Airway Biology and Disease Program. Focuses on basic and clinical research, education and training related to chronic obstructive pulmonary diseases, asthma, cystic fibrosis, control of breathing, bronchiolitis, respiratory neurobiology, sleep, and other adult airway diseases.

Lung Biology and Disease Program. Supports research, education, and training programs in lung cell and vascular biology; lung growth and development and pediatric lung disease; acute lung injury and critical care medicine; interstitial lung diseases, including pulmonary fibrosis; and AIDS and tuberculosis.

For examples of areas of interest, see NHLBI Topics.pdf.

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Blood Diseases and Resources

The NHLBI Division of Blood Diseases and Resources (DBDR) plans and directs an integrated research and training program, with an emphasis on non-malignant blood diseases such as Cooley's anemia, sickle cell disease, hemophilia, hemochromatosis, and disorders of hemostasis and thrombosis. A program in hematopoietic stem cell biology and transplantation focuses on use of transplantation to treat blood diseases, coordination of clinical transplant research, and identification of new research opportunities. The Division also has a major responsibility to improve the adequacy and safety of the nation's blood supply through research in transfusion medicine. Two programs comprise the DBDR, the Blood Diseases Program, and the Blood Resources Program.

Blood Diseases Program. Supports research and training in nonmalignant disorders of blood cells and the hematopoietic system.

Blood Resources Program. Supports research and training in blood and marrow transplantation, thrombosis and hemostasis, and, transfusion medicine. For examples of areas of interest, see NHLBI Topics.pdf.

Epidemiology and Clinical Applications

The NHLBI Division of Epidemiology and Clinical Applications (DECA) plans and directs programs in epidemiologic studies, basic and applied behavioral research, demonstration and education research, and projects for disease prevention and health promotion, including large scale clinical trials. The research supported by the Division provides multidisciplinary approaches to heart and blood vessel, lung, and blood diseases, with a primary focus on cardiovascular disease.

DECA is comprised of two programs, the Clinical Applications and Prevention Program and the Epidemiology and Biometry Program, and the Office of Biostatistics Research.

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A. *Clinical Applications and Prevention Program*. Supports research into prevention of heart and vascular, pulmonary, and blood diseases through activities such as clinical trials, health promotion-disease prevention, community interventions, health education research, nutrition research, and behavioral medicine.

B. *Epidemiology and Biometry Program*. Supports and conducts epidemiological studies of heart and vascular, lung, and blood diseases in defined populations in the United States and other countries.

For examples of areas of interest, see NHLBI Topics.pdf.

Other Research Topic(s) Within the Mission of Institute

For administrative and business management questions, contact:

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NATIONAL HUMAN GENOME RESEARCH INSTITUTE (NHGRI)

The Human Genome Project (HGP) is an international initiative involving the NIH and several other federal, private, and international organizations. At the NIH, the NHGRI is the lead institute for the HGP. Many of the initial goals of this project--genetic and physical maps of the mouse and human, and the DNA sequences of E. coli, S. cerevisiae, C. elegans and D. melanogaster--have been realized. A working draft version of at least 90% of the euchromatic part of the human genome was completed in 2000, and the complete high quality human sequence will follow within the next couple of years. More than 25% of the human genome sequence has been finished, including all of chromosomes 21 and 22. Mouse genome sequencing has also begun; an intermediate version will be generated within the

next year and the complete sequence will follow by 2004 or sooner.

Once the DNA sequence of an organism becomes available, many new avenues to studying its biology are opened. However, new and improved research tools, approaches, and capabilities are needed to discover and use the vast amount of biological information in complete genomic DNA sequences. In 1998, a set of new goals was adopted for the U.S. Human Genome Program (see Goals at http://www.nhgri.nih.gov/98plan/). In addition to completing the human and mouse maps and sequences, the aim of the HGP was extended to developing new technological approaches that will be necessary to understand and use genomic DNA sequence. Therefore, important areas of attention for the NHGRI will be the continued development of new technology for mapping and sequencing, for the interpretation of genomic sequence, including functional analysis of non-coding sequences, for the study of sequence variation, and for the analysis of gene expression. Support for scholarly research as the foundation for understanding the ethical, legal and social implications (ELSI) of genomics and genetics research will also continue to be a major area of emphasis.

The success of the Human Genome Project has been due to the development of improved technologies, strategies and methods that can be applied on a genome-wide scale in a cost-effective manner. As part of its interest in continuing to provide support for technology development research and, therefore, the NHGRI solicits SBIR/STTR grant applications in the areas listed below. Innovative approaches in other areas not listed in the major topics below will also be seriously considered.

DNA Sequencing

Development of (1) innovative technologies and strategies that promise to reduce the cost, increase the throughput, or improve the accuracy of large-scale DNA sequencing of complex genomes; (2) strategies and technologies for obtaining DNA sequence in the gaps that are left by current sequencing methods or that will improve the efficiency of sequencing in genomic regions that have proved difficult to sequence due to limitations in available cloning and sequencing technology; (3) innovative sequencing technologies and strategies for SNP detection; and (4) instrumentation and methods development, from technical feasibility through prototype development and introduction into production.

Human Genome Sequence Variation

Development of new or improved methods and analytic tools for: (1) the large-scale identification, scoring, and interpretation of DNA sequence variants; (2) the identification of haplotypes; and (3) facilitation of studies relating the distribution of variation to population history in order to determine the density of SNPs or other markers needed for gene mapping.

Comparative Genomics

Improvement in the technology for generating clone libraries useful for genomic analysis with DNA inserts that are stable, free of artifacts, and faithfully representative of genomic DNA from complex organisms. Generation of (1) clone libraries of additional commonly used mouse strains; (2) mapping resources for the mouse; (3) a low resolution (5cM) single nucleotide polymorphism (SNP) map to determine the usefulness of this resource for studying complex diseases in the mouse; and (4) genetic maps of additional commonly used mouse strains using single sequence length polymorphisms as markers.

Functional Genomics

(1) Development of new or improved technologies for large-scale or genome-wide approaches relating to: gene discovery, full-length cDNA synthesis, or gene expression analysis;(2) analysis of protein-ligand interactions, such as protein-protein interactions; protein modifications; (3) functional analyses of non-coding sequences; and (4) generation and detection of mutations.

Bioinformatics and Computational Biology

Development of new or improved tools for: (1) obtaining, representing, analyzing and archiving data and (2) improving databases, in the areas of DNA sequence, gene mapping, complex trait analysis, genetic variation and homology, and functional genomics.

Ethical, Legal and Social Implications (ELSI) of Genomics and Genetics Research

Examination of: (1) the issues surrounding the completion of the human DNA sequence and the study of human sequence variation raised by the integration of genetic technologies and information into health care and public health activities and (2) the integration of knowledge about genomics and gene-environment interactions into non-clinical settings.

Other Research Topic(s) Within Mission of Institute

Individuals interested in any of the above listed areas are encouraged to contact the NHGRI staff listed below. For more specific information about areas of interest to the NHGRI, please visit our home page at http://www.nhgri.nih.gov/Grant_info**.**

For additional information on research topics, contact:

For all research topics except ELSI

Dr. Bettie J. Graham
National Human Genome Research Institute
(301) 496-7531; Fax: (301) 480-2770
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For ELSI research topics

Elizabeth Thomson, R.N., M.S.
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(301) 402-4997; Fax: (301) 402-1950
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For administrative and business management questions, contact:

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NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

The mission of the National Institute of Mental Health (NIMH) is to diminish the burden of mental illness through research. To achieve this goal, the NIMH funds basic research, clinical studies, and services delivery research concerning any aspect of behavioral and mental disorders (including HIV prevention and neuro-AIDS research). Ultimately, this research will lead to greater understanding, better treatment and rehabilitation or prevention of mental disorders. The NIMH is also concerned with the speedy dissemination and use of this knowledge through scientific communications and public education, and in its more effective implementation in practice and service delivery systems. There is a general need to develop reliable and inexpensive equipment, and other products, that can serve these needs.

For additional information about areas of interest to the NIMH, please visit our home page at http://www.nimh.nih.gov.

Division of Neuroscience and Basic Behavioral Science

Through research in neuroscience and basic behavioral science we can gain an understanding of the fundamental mechanisms underlying thought, emotion, and behavior—and an understanding of what goes wrong in the brain in mental illness. Research sponsored by the Division of Neuroscience and Basic Behavioral Science covers a broad range of neuroscience topics: from both experimental and theoretical approaches, from molecules to whole brains to populations of individuals, from single cell organisms to humans, from across the entire lifespan, and from states of health and disease. This division also supports research on the basic behavioral, psychological, and social processes that underlie normal behavioral functioning. The topics listed below reflect the NIMH interest in technologies related to this broad range, but should not be considered to be a complete list. Prospective applicants are strongly encouraged to contact Dr. Michael Huerta with questions about the relevance of their interests to the mission of this division.

A. *Cutting-edge technologies and approaches for neuroscience research,* including, but not limited to, caged molecules, genetically engineered proteins; inducible gene expression; combinatorial approaches; biosilicon devices; biocompatible biomaterials; nanotechnologies; acousto-optics and opto-electronics; imaging technologies; informatics tools; simulation technologies; mathematical and computer algorithms; telemetry; and biosensors. For examples of areas of interest, see NIMH Topics.pdf.

B. *Instrumentation for Basic and Clinical Neuroscience Research.* Modern equipment that uses the most recent technological advances is needed in neuroscience research so that neural substrates of mental illness can be identified and localized. For examples of areas of interest, see NIMH Topics.pdf.

C. *Macroscopic Neuroimaging*. Modern technologies allow for the observation of the structure and function of the intact brain. This capability has the potential to greatly advance understanding of the brain in both health and disease, and across the lifespan. NIMH is interested in advancing this area of technology through enhancing current tools and approaches, as well as developing entirely new ways to image the brain. All modalities are of interest, including, but not limited to: magnetic resonance imaging (MRI) or spectroscopy, positron emission tomography (PET), optical imaging or spectroscopy, single photon emission computed tomography, etc. Due to its greatly increased use in recent years, technologies specifically focused on improving the utility of fMRI techniques are of particular interest. For examples of areas of interest, see NIMH Topics.pdf.

D. *Microscopic Neuroimaging.* The morphology of individual neurons and the distribution of subcellular components within them, are key to understanding the manner in which these cells function. Advances in microscopy and in the development of agents indicating neuronal structure and function that can be visualized microscopically are important to the NIMH's interest in brain research. This includes novel devices and approaches (single and multi-photon, tunneling, confocal, etc.); enhancements of current technologies, agents and ligands to be imaged (agents indicating specific biochemical processes or structures, etc.); software to assist interaction with the instrument or data; and other related technologies and methods. For examples of areas of interest, see NIMH Topics.pdf.

E. *Molecular and Cellular Neurobiology and Neurochemistry*. Manipulating and studying basic molecular, cellular and chemical processes has led to insight to understanding brain function, and has provided the foundation on which pharmacological interventions have been developed for the treatment of mental illness. NIMH is interested in supporting a wide range of new techniques and tools related to this area. For examples of areas of interest, see NIMH Topics.pdf.

F. *Genetic and Transgenic Technology*. Advances in genetic and transgenic technologies offer many opportunities to probe fundamental questions about the brain, behavior and pathology. For examples of areas of interest, see NIMH Topics.pdf.

G. *Neuroimmunology*. Research on the interplay between the brain, neuroendocrine system, and, immune system has revealed important links between these major homeostatic system components. For examples of areas of interest, see NIMH Topics.pdf.

H. *Pharmacology*. Pharmacological intervention represents a major force in the treatment of mental illness, and NIMH is interested in supporting research and development in this area. For examples of areas of interest, see NIMH Topics.pdf.

I. *Tract Tracing Methods and Tools*. Little is known about the details of the connectivity of the human nervous system, because the best tract tracing techniques are invasive and require the deposit of substances in vivo. Methods that would be applicable to post-mortem tissue would allow significant progress in connectional studies of human tissue, as well as non-human tissue, particularly with regard to the development of connections and the connections of structures not easily accessed in vivo.

J. *Basic Behavioral Science*. It is important to develop reliable methods that can correctly identify the normal and abnormal components of cognitive, emotional, and psychosocial behavior in human development. Computer based methods of accomplishing this are also needed to increase the accessibility and reliability of information made available to the research community. For examples of areas of interest, see NIMH Topics.pdf.

K. *Educational Tools*. Neuroscience and basic behavioral science area compelling areas of science that not only touches upon a diverse array of disciplines, but also

provides insights to the essence of what it is to be human. Products aimed at teaching the substance of these fields to students of all ages would be useful in disseminating this information and these insights. Examples include, but are not limited to: software and other interactive media used to convey fundamental concepts about the brain to children; computer simulations of neuroscience experiments; updateable media that presents state-of-the-art information on particular topics for use by experts; website or other online, interactive electronic vehicle to allow for sharing of information about the brain and its functions, including technologies for holding interactive research conferences related to basic behavioral sciences, basic neuroscience, or clinical neuroscience.

L. *Neuroinformatics.* Data generated by brain research are diverse, vast, and complex. The diversity of data is due to the fact that neuroscience data are obtained from: theoretical, experimental and clinical approaches; from levels of biological organization that span molecules to populations of individuals and from single-cell organisms to humans; and from states of health, disease, and models of disease. The quantity of data in brain research is the result of tens of thousands of neuroscience laboratories working around the world. The complexity of data reflects the high level of interconnectedness of the data, and their high dimensionality. Neuroinformatics is a new area of science that draws upon neuroscience, information science, computer science, statistics, applied mathematics, and a variety of engineering fields to develop tools that will let neuroscientists make better sense and use of their data. These tools include software and hardware for digital data acquisition, visualization, analysis, integration, and sharing (e.g., through tools for electronic scientific collaboration). Such tools can address data of any type or from any area of neuroscience. For examples of areas of interest, see NIMH Topics.pdf.

For further information on basic and clinical neuroscience or basic behavioral science research topics, contact:

Michael Huerta, Ph.D.
Associate Director
Division of Neuroscience and Basic Behavioral Science
National Institute of Mental Health
6001 Executive Blvd. Room 7201
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Division of Mental Disorders, Behavior and AIDS

The Division of Mental Disorders, Behavior and AIDS is responsible for planning, directing and supporting programs of research, research training, research dissemination and resource development in behavioral science, developmental psychopathology, prevention and early intervention, and in research on the causes of and prevention of HIV (AIDS). The division is comprised of the Center for Mental Health Research on AIDS and three branches: the Developmental Psychopathology and Prevention Research Branch; the Adult Psychopathology and Prevention Research Branch and the Health and Behavioral Science Research Branch.

The Center for Mental Health Research on AIDS. This Center plans coordinates, and supports biomedical and behavioral research designed to develop a better understanding of the biological and behavioral causes of HIV (AIDS virus) infection, and more effective mechanisms for the diagnosis, treatment, and prevention of AIDS. The Center is also interested in identifying and addressing behavioral issues in vaccine trials and in identifying the effects of HIV infection on the central nervous system.

Developmental Psychopathology and Prevention Research Branch. The focus of this branch is on: risk/protective factor identification; early social, emotional and cognitive developmental processes leading to psychopathology or resilience and the translation of risk and developmental research into new prevention, early intervention and treatment strategies. Studies may address modifiable and potent individual, social, cultural and environmental factors and processes; critical dimensions of behavioral expression that confer risk such as emotion regulation, and impulse control and executive functions.

Adult Psychopathology and Prevention Research Branch. This branch focuses on research that reflects significant public health concerns. These include: developing preventive interventions for adult psychopathology which are based upon epidemiologic and clinical research, refining assessment and diagnosis of adult psychopathology and disability and clarifying the relations among psychological, biological, social, cultural and environmental factors involved in adult mental illness and disability.

Health and Behavioral Science Research Branch. This branch supports research on general medical illnesses and behavior and their relationship to mental disorders. Emphasis is on the mechanisms and processes linking medical and mental illnesses, development and testing of early interventions, factors that influence adherence to treatment, help seeking behavior, cognitive and decision making factors that influence the choice of treatment or mental health services, stigma and services utilization.

All applications relevant to the mission of the Division of Mental Disorders, Behavior and AIDS will receive full consideration. **Possible areas for future research include**:

A. *Instrumentation for basic and clinical behavioral research*. Modern equipment that uses the most recent technological advances is needed so that mental disease can be related to dysfunction(s) of the CNS. Once these dysfunctions are identified and localized, rational therapies can be developed and evaluated.

B. *Behavioral science, research and development*. It is important to develop reliable methods that can correctly identify the normal and abnormal components of cognitive, emotional, and psychosocial behavior in human development. Computer based methods of accomplishing this are also needed to increase the accessibility and reliability of information made available to the research community.

C. *Health and behavior and prevention*.

D. *Science education in mental disorders, behavior and AIDS*. There is a critical need for improvement in science education, particularly in areas specifically related to brain, behavior and mental illness.

E. *Diagnosis and assessment of emotional and psychological states*.

F. *Knowledge transfer approaches*.

For examples of areas of interest, see NIMH Topics.pdf.

NIMH Center for Mental Health Research on AIDS

The NIMH office on AIDS Research supports research on the effects of HIV on the central nervous system and on developing effective HIV prevention and risk reduction interventions. Examples of possible SBIR initiatives include, but are not limited to:

A. Behavior Change and Prevention Strategies to reduce HIV transmission especially among minority populations and hard to reach subsets of those populations.

B. Neuro-AIDS: HIV-1 Infection and the Nervous System

C. AIDS Mental Health Services Delivery

For examples of areas of interest, see NIMH Topics.pdf.

For further information on mental disorders, behavior, or AIDS research topics, contact:

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Bethesda, Maryland 20892-9621
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Division of Services and Intervention Research

The Division of Services and Interventions Research supports research, research demonstrations, research training, resource development, and research dissemination in prevention and treatment interventions, services research, clinical epidemiology, and diagnostic and disability assessment. The division is comprised of three branches: Services Research and Clinical Epidemiology Branch, Adult and Geriatric Treatment and Preventive Intervention Research Branch, and Child and Adolescent Treatment and Preventive Intervention Research Branch.

CLINICAL TRIALS, CLINICAL PRACTICE, AND EFFECTIVENESS RESEARCH

This division is concerned with both the translation of neuroscience and behavioral science knowledge into clinical practice and with the development of research on the effectiveness of treatment and rehabilitation. This involves clinical and clinical services research on the delivery of mental health services in hospitals, clinics, communities, and in a wide variety of systems of care, e.g., managed care, primary care, etc.

A. *Services Research and Clinical Epidemiology Branch*. This branch supports research on the organization, financing, delivery, effectiveness, and appropriateness of mental health care in everyday settings in order to find ways to improve the effectiveness, efficiency, and equity of mental health services (including preventive services) in community and other settings. Also supported are studies on pharmacoeconomics, pharmacoepidemiology, and the distribution, determinants, and course of mental illness in the context of various clinical settings. Mental health services include mental health care provided in specialty mental health and general health care settings, including primary care, hospitals, nursing homes, and other residential care settings, as well as in educational settings and various legal system settings, such as jails, juvenile detention and correctional facilities, prisons, and probation and parole programs. Other services often needed by mentally ill persons include social services, vocational and rehabilitation services, welfare, and housing. Relevant services include those provided to children and adolescents with emotional disorders, adults and elderly adults with mental disorders, and persons with mental illness that co-occurs with physical illness and with alcohol and/or drug abuse disorder. Research methodologies include ethnographic studies, surveys, and analyses of secondary data, randomized controlled trials, quasi-experimental designs, cohort, and case-control studies.

   Advances in clinical epidemiology, mental health treatment and services research fields have made it imperative that intensive work continue in the areas of assessment/screening technologies, outcome assessment measurement and measurement packages, dissemination technologies, data analysis techniques, and the training of clinicians and providers. The translation of efficacious and effective treatments into primary care, community mental health centers, and managed care settings is both a major challenge and opportunity to develop technologies and systems that will improve the care and rehabilitation of patients and enable them to profit from the research advances that have been made. Research is needed on the dissemination of empirically supported treatments or services.

For examples of areas of interest, see NIMH Topics.pdf.

B. *Adult and Geriatric Treatment and Preventive Interventions Research*. The focus is on the treatment, prevention, and rehabilitation of mental disorders in adults, including older persons. The focus is broad and inclusive with respect to the heterogeneity of patients, the severity and chronicity of disorders, the variety of community and institutional settings in which treatment is provided, and the range of outcomes measured. Disorders studied include: all mental disorders; Alzheimer's disease and related dementias; suicide; eating disorders, sleep disorders; and disorders related to the menstrual cycle. Interventions studied include pharmacologic approaches (individual drugs and combinations of drugs), somatic approaches (e.g., electroconvulsive therapy), behavioral and psychotherapeutic approaches (e.g., cognitive therapy). Research is supported on individual and combined approaches; time frame includes acute, continuation, and maintenance studies and long-term symptomatic management and improvement of functional status.

   Human subjects include adult and geriatric age groups covering the full range of mental disorders individually and in complex patterns of comorbidity with other mental disorders (e.g., anxiety + depression), substance abuse (e.g., depression + alcohol abuse), brain disease (e.g., stroke + depression), or physical illnesses (e.g., sensory impairment + psychosis). Normal controls are often used

in studies. Settings of research include academic or non-academic specialty services (psychiatry, neurology, etc.), primary care settings, hospitals, nursing homes, outpatient clinics, and home health under managed care or fee-for-service. Other settings for research include occupational health programs, community centers, and correctional facilities. Research must include active interventions for mental disorders and behavioral dysfunctions; observational studies are assigned elsewhere. Areas supported are: trials to establish the short- and long-term efficacy of interventions; studies that assess the effectiveness/cost effectiveness of interventions in standard or usual practice settings; off-label or innovative applications of established treatments; comparative studies of alternative treatments; clinical pharmacokinetic/ pharmacodynamic studies; strategies for augmentation/combination and for reduction/taper; correlates of treatment response/basis for treatment failure with established agents; studies designed to develop and refine methodology for use in intervention research; and treatment algorithms/strategies for improvement of clinical care.

For examples of areas of interest, see NIMH Topics.pdf.

C. *Child and Adolescent Treatment and Preventive Intervention Research*. The branch supports research focusing on the treatment, prevention, and rehabilitation of mental disorders in children and adolescents. The focus is broad and inclusive with respect to the heterogeneity of patients, the severity and chronicity of disorders, the variety of community and institutional settings in which treatment is provided and the range of outcomes measured. Disorders studied include all mental and behavioral disorders. Interventions studied include pharmacologic approaches (individual and combination medications), somatic approaches, behavioral and psychotherapeutic approaches. Research is supported on individual and combined approaches, time-frame includes acute, continuation, and maintenance studies and long-term symptomatic management and improvement of functional status. Human subjects include child and adolescent age groups covering the full range of mental disorders individually and in complex patterns of comorbidity with other mental disorders and behavioral problems (e.g., anxiety and depression), substance abuse (e.g., depression and alcohol abuse), brain disease or physical illnesses. Normal controls are often used in studies. Settings of research include academic or non-academic services (child psychiatry, neurology, etc.), primary care settings (e.g, pediatrics), hospitals, group homes, foster care, schools, and outpatient clinics under managed care or fee-for-service. Other settings include community centers, group homes and juvenile justice facilities. Research must include active interventions for mental disorders and behavioral dysfunctions; observational studies are assigned elsewhere. Areas supported are: trials to establish the short- and long-term efficacy of interventions; studies that assess the effectiveness/cost effectiveness of interventions in standard or usual practice settings; off-label or innovative applications of established interventions; comparative studies of alternative interventions; clinical pharmacokinetic/pharmacodynamic studies; strategies for augmentation/ combination and for reduction/taper; correlates of treatment response/basis for treatment failure with established agents; treatment algorithms/strategies for improvement of clinical care; and studies designed to develop and refine methodology for use in intervention research.

For further information on services and intervention research, contact:

Dr. Kenneth G. Lutterman
Division of Services and Intervention Research
6001 Executive Boulevard,
Room 7112, MSC 2629
Bethesda, MD 20892-9629
(301) 443 3648; Fax: (301) 443 4045

Other Research Topic(s) Within Mission of Institute

For general questions about the mission of NIMH, prospective applicants are encouraged to contact:

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Division of Neuroscience and Basic Behavioral Science
National Institute of Mental Health, NIH
6001 Executive Blvd. Room 7202
Mail Stop Code 9645
Rockville, MD 20852
(301) 443-3563; Fax: (301) 443-1731
Email: mmhuerta@helix.nih.gov

For administrative and business management questions, contact:

Mr. Michael Loewe
Grants Management Branch
National Institute of Child Health and Human Development
6100 Executive Boulevard
Room 8A17J
Rockville, MD 20852
(301) 435-7008; Fax: (301) 402-0915

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS)

The mission of NINDS is to reduce the burden of neurological disease - a burden borne by every age group, by every segment of society, by people all over the world. To this end, the Institute supports and conducts research on the healthy and diseased brain, spinal cord, and peripheral nerves. Hundreds of disorders afflict the nervous system. Common killers and disablers such as Parkinson's disease, Alzheimer's disease, multiple sclerosis, stroke, epilepsy, and autism are well known. Other disorders we study may be known only to the patients and families affected, their doctors, and scientists who look to rare disorders for help in understanding the brain as well as treating more common diseases.

For additional information about areas of interest to the NINDS, please visit our home page at http://www.ninds.nih.gov/.

NINDS supports research in the following programmatic areas:

Neurodevelopment

Dr. Deborah Hirtz
(301) 496-5821; Fax: (301) 402-1501
Email: dh83f@nih.gov

Neurogentics

Dr. Robert Finkelstein
(301) 496-5745: Fax: (301) 402-1501
Email: rf45c@nih.gov

Repair and plasticity

Dr. William Heetderks
(301) 496-1447; Fax: (301) 480-1080
Email: wh7q@nih.gov

Synapses and circuits

Dr. Cheryl Kitt
(301) 496-9964; Fax: (301) 480-2424
Email: cheryl_kitt@nih.gov

Systems and cognitive neuroscience

Dr. Cheryl Kitt
(301) 496-9964; Fax: (301) 480-2424
Email: cheryl_kitt@nih.gov

Neurodegeneration

Dr. Eugene Oliver
(301) 496-9135; Fax: (301) 480-1080
Email: oliverg@ninds.nih.gov

Neural environment

Dr. Thomas P. Jacobs
(301) 496-1431; Fax: (301) 480-2424
Email: thomas_jacobs@nih.gov

Technology development (e.g., animal models, neuroinformatics, computational tools, and imaging tools.)

Dr. Robert W. Baughman
(301) 496-1779: Fax (301) 402-1501
Email: rb175y@nih.gov

For examples of areas of interest, within each of these programmatic areas, see NINDS Topics.pdf.

Other Research Topics Within Missions of Institute

For program information, contact:

Dr. Thomas Miller
Program Analyst
6001 Executive Boulevard, Room 2139
Bethesda, MD 20892

(301) 496-1779; Fax: (301) 402-1501
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For administrative and business management questions, contact:

Ms. Kathleen Howe
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Email: kh52x@nih.gov

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

The NINR supports research focused on biological and behavioral aspects of critical health problems that confront the Nation. Emphasis is on seeking ways to reduce the burden of illness and disability by understanding and easing the effects of acute and chronic illness, improving health-related quality of life by preventing or delaying the onset of disease or slowing its progression, establishing better approaches to promote health and prevent disease, and improving clinical environments by testing interventions that influence patient health outcomes and reduce costs and demand for care. For additional information about areas of interest to the NINR, please visit our home page at http://www.nih.gov/ninr/.

NINR invites applications containing innovative ideas and sound methodology in all aspects of nursing research consistent with the NINR mission. A major program priority is the integration of biological and behavioral research. Three dimensions - promoting health and preventing disease, managing the symptoms and disability of illness, and improving the environments in which care is delivered - cut across six broad science areas supported by NINR. Emphasis is on:

Research and Development of Technologies that Promote Alleviation, Adaptation, or Management of Symptoms

Research and Development of Technologies to Enhance Self Care and Clinical Care

For examples of areas of interest, see NINR Topics.pdf.

Other Research Topic(s) Within the Mission of Institute

For additional information on research topics, contact:

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National Institute of Nursing Research
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For administrative and business management questions, contact:

Ms. Cindy McDermott
Grants Management Officer
National Institute of Nursing Research
(301) 594-6869; Fax: (301) 480-8260
Email: cm253t@nih.gov

NATIONAL CENTER FOR RESEARCH RESOURCES (NCRR)

The NCRR develops and supports critical research technologies and shared resources that underpin research to maintain and improve the health of our Nation's citizens.

For additional information about areas of interest to the NCRR, please visit our home page at http://www.ncrr.nih.gov/.

Emphasis is on:

Research and Development in Instrumentation and Specialized Technologies for Biomedical Research

Electron Microscopy, X-ray Diffraction, Other Topics
Dr. Amy Swain
Biomedical Technology
National Center for Research Resources
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Imaging, EPR
Dr. Abraham Levy
Biomedical Technolog
National Center for Research Resources
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NMR, Optical Microscopy, Laser Applications
Dr. Gregory Farber
Biomedical Technology
National Center for Research Resources
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Mass Spectrometry
Dr. Douglas Sheeley
Biomedical Technology
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Research and Development in Comparative Medicine

Dr. Franziska B. Grieder
Comparative Medicine
National Center for Research Resources
(301) 435-0744; Fax: (301) 480-3819
Email: fg45v@nih.gov

Clinical Technology Applications

Dr. Geoffrey P. Cheung
Clinical Research National Center for Research Resources
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Development of Discovery-Oriented Software for Science Education

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For examples of areas of interest, see NCRR Topics.pdf.

Other Research Topic(s) Within Mission of Center

For additional information on research topics, contact:

Dr. Louise Ramm
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(301) 435-0879; Fax: (301) 480-3658
Email: lr34m@nih.gov

For administrative and business management questions, contact:

Mr. Bryan Clark
National Center for Research Resources
(301) 435-0848; Fax: (301) 480-3777
Email: ClarkB@ncrr.nih.gov

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE (NCCAM)

"The general purposes of the National Center for Complementary and Alternative Medicine (NCCAM) are the conduct and support of basic and applied research … research training, … and other programs with respect to identifying, investigating, and validating complementary and alternative treatment, diagnostic, and prevention modalities, disciples and systems" (P.L. 105-277). To meet this mandate, NCCAM supports research and training programs that increase our knowledge of, and improve research methods on, complementary and alternative medicine.

For additional information about areas of interest to the NCCAM, please visit our home page at http://nccam.nih.gov.

Emphasis is on

Education and Public Information

Patient Management

Botanical Products

Research-Related issues

For examples of areas of interest, see NCCAM Topics.pdf.

Other Research Topic(s) Within Mission of the Center

For additional information on research topics, contact:

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Building 31/Room 5B58
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For administrative and business management questions, contact:

Ms. Suzanne White
Grants Management Specialist
2 Rockledge Center
6701 Rockledge Drive, Room 7150
Bethesda, MD 20892-7926
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NATIONAL LIBRARY OF MEDICINE (NLM)

The NLM supports research on the organization, management, and utilization of health knowledge and information. Volume and demand for health science knowledge overwhelm traditional methods of information access for health professionals. Clinician, investigator, and student find it increasingly difficult to integrate vast bodies of data. Innovative methods, systems, and services for managing information that incorporate speed, responsiveness, and economy are needed. State-of the-art computer and communication technologies offer opportunities for the creative development of such information access mechanisms for health professionals, their students, and their patients.

For additional information about areas of interest to the NLM, please visit our home page at http://www.nlm.nih.gov.

Molecular Biology

The appearance of new experimental methods has greatly increased the volume of molecular data for all the basic medical sciences, including the neurosciences. For examples of areas of interest, see NLM Topics.pdf.

Medical Informatics

There are broad needs for innovative computer software and systems to assist changing dimensions of health care by developing knowledge bases, information synthesizing mechanisms, decision support systems, and similar modalities. For examples of areas of interest, see NLM Topics.pdf.

Other Research Topic(s) Within Mission of NLM

For additional information on research topics, contact:

Mr. Milton Corn
National Library of Medicine
(301) 496-3113; Fax: (301) 402-2952
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For administrative and business management questions, contact:

Mr. Christopher Robey
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National Library of Medicine
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TRANS-NIH RESEARCH PROGRAMS

Development of Synthetic and Natural Biomaterial Reference Materials

The NIH invites applications for the development of synthetic or natural biomaterial reference materials (RMs). RMs are used for standardization of studies of interactions between materials and blood and tissues, for calibration of physicochemical test methods, and/or for reference controls in physical, chemical, and materials structure characterization tests. All innovative developments of biomaterials and devices also need measurements to demonstrate their innovation and improvement. Because RMs lie at the heart of measurement technology, funding for their development could play a key role in future advances in biomaterials and biomedical material device technologies. For examples of areas of interest, see Trans NIH Research Program Topics.pdf.

National Center on Sleep Disorders Research

The National Center on Sleep Disorders Research (NCSDR) was established within the National Heart, Lung, and Blood Institute (NHLBI) as a result of the National Institutes of Health (NIH) Revitalization Act of 1993. Its mandate is to conduct and support research, training, health information dissemination, and other activities with respect to sleep disorders, including biological and circadian rhythm research, basic understanding of sleep,

chronobiological and other sleep related research and to coordinate the activities of the Center with similar activities of other Federal agencies, including the other agencies of the National Institutes of Health, and similar activities of other public entities and nonprofit entities.

Three specific types of research are emphasized: basic research, using state-of-the-art approaches, to elucidate the functions of sleep and the fundamental molecular and cellular processes underlying sleep; patient-oriented research to understand the cause, evaluate the scope, and improve the diagnosis and treatment of sleep disorders; and applied research to evaluate the scope and consequences of sleepiness and to develop new approaches to prevent impaired performance during waking hours. For examples of areas of interest, see Trans NIH Research Program Topics.pdf.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The CDC serves as the national focus for developing and applying disease prevention and control, environmental health and health promotion and health education activities designed to improve the health of the people of the United States. To accomplish its mission, CDC identifies and defines preventable health problems and maintains active surveillance of diseases through epidemiologic and laboratory investigations and data collection, analysis, and distribution; serves as the PHS lead agency in developing and implementing operational research aimed at developing and testing effective disease prevention, control and health promotion programs; administers a national program to develop recommended occupational safety and health standards and to conduct research, training, and technical assistance to assure safe and healthful working conditions for every working person; develops and implements a program to sustain a strong national workforce in disease prevention and control; conducts a national program for improving the performance of clinical laboratories; and develops programs to prevent premature death and avoidable illness and disability caused by noninfectious, non-occupational environmental and related factors.

CDC is responsible for controlling the induction and spread of infectious diseases, and provides consultation and assistance to other nations and international agencies to assist in improving their disease prevention and control, environmental health, and health promotion activities.

For additional information about areas of interest to the CDC, please visit our home page at http://www.cdc.gov/.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)

NIOSH will accept SBIR grant applications ONLY on the August 1 and December 1, 2001 receipt dates.

The NIOSH plans, directs and coordinates the national program effort to develop and establish recommended occupational safety and health standards and to conduct research, training, and related activities to assure safe and healthful working conditions for every working man and woman. NIOSH has both a regular grant program and an SBIR grant program; the purpose of both is to develop knowledge that can be used in preventing occupational diseases and injuries. In the regular NIOSH grant program, the following types of applied research projects are supported: causal research to identify and investigate the relationships between hazardous working conditions and associated occupational diseases and injuries; methods research to develop more sensitive means of evaluating hazards at work sites, as well as methods for measuring early markers of adverse health effects and injuries; control research to develop new protective equipment, engineering control technology, and work practices to reduce the risks of occupational hazards; and demonstrations to evaluate the technical feasibility or application of a new or improved occupational safety and health procedure, method, technique, or system.

Control Technology and Personal Protective Equipment

Engineering controls, administrative policies, and personal protective equipment are needed to manage exposures to occupational hazards. Engineering controls include substitution of a safe material for a hazardous one, design changes to equipment, or modification of work methods to eliminate or reduce hazards.

Changes in work practices and management policies and training programs are examples of administrative controls. In some cases where it is not otherwise possible to maintain a healthy work environment, personal protective equipment such as respirators and protective clothing can be used to isolate workers from the hazard. Research is needed to develop and evaluate control strategies for specific hazards and to assure their practicality and usability in workplaces. For examples of areas of interest, see NIOSH Topics.pdf.

Exposure Assessment Methods

Exposure assessment is a multi-disciplinary field central to deciding whether and how to use resources for reducing workplace exposures, and to defining exposure-response relationships in epidemiologic studies. Rapid, inexpensive measurement tools and improved data analysis methods are needed for the collection of adequate exposure data and for effective intervention. At least three major gaps in current methods will drive development of exposure assessment methods in the next decade: (1) the lack of sufficiently precise exposure assessments to support accurate epidemiologic studies in the complex environments of today's workplaces, (2) the lack of practical measurement techniques that can be applied at reasonable cost in many workplaces where hazards may exist, and (3) the lack of validated methods for measuring relevant exposure and total dose data directly from biological samples obtained by relatively noninvasive techniques. For examples of areas of interest, see NIOSH Topics.pdf.

Intervention Effectiveness Research

The goal of intervention research is to develop practical strategies and techniques that effectively reduce or prevent workplace injuries and illnesses. Workplace safety and health interventions include but are not limited to developing and implementing specific engineering control technologies, process and work organization changes, information dissemination and health communication practices, worker/management participatory safety and health programs, safety and health training, selective use of personal protective equipment, and inspection and enforcement of protective exposure limits. Intervention research involves the testing and evaluation of interventions, programs, and policies. Although many intervention strategies have been applied to industrial settings, knowledge about what works best is limited. Corporate safety and health programs, regulatory requirements and voluntary consensus standards, workers' compensation policies and loss-control programs, engineering controls, and educational campaigns are among the types of interventions that need to be developed, implemented, and evaluated. For examples of areas of interest, see NIOSH Topics.pdf.

Surveillance Research Methods

Surveillance systems describe where occupational hazards, injuries, or illnesses are found, how frequently they are found, whether they are increasing or decreasing, and whether prevention efforts have been effective. The public health community relies on surveillance information to set research and prevention priorities, but critical gaps in current systems limit their usefulness. These systems need to be updated and expanded, and new systems and methodologies need to be developed. For examples of areas of interest, see NIOSH Topics.pdf.

Other Research Topic(s) Within Mission of Institute

For technical information on research topics contact:

Dr. Roy Fleming
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health
Mail Stop D30
1600 Clifton Road, N.E.
Atlanta, Georgia 30333
(404) 639-2810; Fax: (404) 639-2196
Email: rmf2@niood1.em.cdc.gov

For administrative and business management information contact:

Joanne Wojcik
Centers for Disease Control and Prevention
Procurement and Grants Office
Mail Stop E13
2920 Brandywine Road
Atlanta, Georgia 30341
(770) 488-2717; Fax: (770) 488-2777
Email: jcw6@cdc.gov

NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL (NCIPC)

NCIPC will accept SBIR grant applications ONLY on the August 1 and December 1, 2001 receipt dates.

The National Center for Injury Prevention and Control plans, directs, and coordinates a national program to maintain and improve the health of the American people by preventing premature death and disability and reducing human suffering and medical costs caused by non-occupational injury, addressing both intentional injuries that result from violent and abusive behavior and unintentional injuries. The national program encompasses the prevention of non-occupational injuries, and applied research and evaluations in acute care and rehabilitation of injured persons. The Center will address injury prevention and control through an orderly sequence of activities beginning with research on causes, circumstances, and risk factors; progressing through research on interventions and their impact on defined populations. These activities then lead to the broad, systematic applications of interventions that are soundly based scientifically.

The CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, a PHS-led national activity for setting priority areas. Potential applicants may obtain a copy of "Healthy People 2010"; (Full Report: Stock No. 017_001_00537_1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (Telephone (202) 512-1800).

The focus of the research topics should reflect the broad-based need to control injury morbidity, mortality, disability, and costs. These projects may be categorized by the three phases of injury prevention and control. These phases are defined below as prevention, acute care, and rehabilitation.

Prevention

There is interest in the development, application, and evaluation of innovative interventions applicable to intentional and unintentional injury. The focus should reflect target populations at high risk for injury and injury consequences, including minorities, children, the elderly, rural residents, and farm families. For examples of areas of interest, see NCIPC Topics.pdf.

Acute Care

The national program encompasses the prevention of non-occupational injuries, and applied research and evaluations in acute care and rehabilitation of injured persons. For examples of areas of interest, see NCIPC Topics.pdf.

Rehabilitation

The national program encompasses the prevention of non-occupational injuries, and applied research and evaluations in acute care and rehabilitation of injured persons. For examples of areas of interest, see NCIPC Topics.pdf.

Other Research Topic(s) Within Mission of Center

For programmatic information, contact:

Mr. Ted Jones
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NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION (NCCDPHP)

The National center for Chronic Disease Prevention and Health Promotion supports a national program to prevent premature death and disability from chronic disease and to promote healthy personal behaviors.

Arthritis and Other Rheumatic Conditions

The Arthritis Program in the Division of Adult and Community Health is working to implement the National Arthritis Action Plan-a Public Health Strategy to decrease the burden of arthritis in the United States. Arthritis is the leading cause of chronic pain and disability in the United States. Opportunities exist to reduce the burden of arthritis and its impact by increasing knowledge of arthritis, self management of arthritis, and the importance of physical activity and weight control among both people with arthritis and health care providers. For examples of areas of interest, see NCCDPHP Topics.pdf.

Other Research Topic(s) Within Mission of Center

Joe Sniezek, M.D., M.P.H.
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Joanne Wojcik
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OFFICE ON SMOKING AND HEALTH

The mission of the Office on Smoking and Health is to lead and coordinate strategic efforts aimed at prevention of tobacco among youth, promoting smoking cessation among youth and adults, and protecting nonsmokers from environmental tobacco smoke. Following recent changes in cigarette warning labels in Canada, there is interest in promoting stronger and larger warning labels in the United States as part of a comprehensive program to reduce initiation and promote cessation of smoking.

Warning labels were first mandated for cigarette packs in 1964, with the expansion to rotating messages in 1984. Research suggests however that warnings as they currently exist may not noticed, and that the messages may be worn out. Canada has had black and white warnings occupying 25% of the front of packs since 1994 and is slated to expand warnings to 50% of the packs in January 2001. In addition to increased size, the new warnings will include color graphics. Research in Canada has demonstrated that persons report that messages that are larger, with strong emotional appeal, and with graphics and pictures are more likely to encourage them to think about stopping (or not starting) smoking. In addition, increasing the size of the message does not have a significant impact on the ability to recognize a "regular brand".

Very limited data on reactions of U.S. citizens to warning labels of different sizes and configurations are available at this time. Such information will be important in providing support for policy change in the United States.

1. Identify consumer response to health warning messages, as it pertains to size, configuration and impact on the decision-making process to smoke or not. The study sample will need to include adult smokers, and teens who are smokers and nonsmokers.
2. Conduct focus groups in US/Canada border areas to obtain information on reactions of U.S. citizens to new Canadian warning labels. Focus groups will include adults and teens, both smokers and nonsmokers.

For programmatic information, contact:

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1600 Clifton Rd, MS K-50
Office on Smoking and Health, NCCDPHP CDC
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For administrative and business information, contact:

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NATIONAL IMMUNIZATION PROGRAM (NIP)

NIP will accept SBIR grant applications on August 1 and December 1, 2001, receipt dates ONLY. Applications for SBIR grants from the National Immunization Program should be submitted to the Bethesda, Maryland address indicated in the application materials, but the application form should be marked prominently: "Please forward promptly to CDC, Atlanta, for technical review by that agency."

The NIP plans, coordinates, directs, and participates in efforts to prevent and reduce illness and premature death through immunization against disease. Activities include:

1. Conducting epidemiology, national surveillance, research and technical consultation on designated diseases for which effective immunizing agents are available and on the safety of vaccines;
2. Assessing immunization levels at national, state, and local levels;
3. Guiding the development of recommendations, guidelines, technologies, and policies for effective, safe, efficient, and economical use of existing vaccines, and for the development and incorporation of new and improved vaccines and associated technologies into disease control programs;
4. Providing technical, epidemiologic, scientific, statistical, financial, programmatic, and administrative assistance to State and local health departments in support of their immunization programs to prevent diseases recommended for vaccination;
5. Implementing national outreach, mobilization, and public information activities to increase understanding about benefits and risks of vaccines, to promote the demand for them, and to improve immunization practices among health care providers;
6. Designing, developing, and implementing information systems to ensure that all persons are properly immunized with the recommended vaccines;
7. Collaborating with the World Health Organization (WHO) and its regional offices and with other CDC Centers/Institutes/Offices (CIOs); in worldwide eradication efforts for polio, and in planning for eradication of other diseases.

Other Research Topic(s) Within the Mission of the Program

For technical information about the needs of the National Immunization Program, contact:

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Vaccine Safety and Development Branch
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For administrative and business management questions concerning SBIR, contact:

Ms. Joanne Wojcik
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NATIONAL CENTER FOR HIV, STD, AND TB PREVENTION (NCHSTP)

NOTICE: Effective February 16, 2001

NCHSTP will not accept SBIR applications in response to the PHS 2001-2 Omnibus Solicitation for SBIR/STTR Grant Applications. These topics have been withdrawn. For additional information, contact Ms. Nina Waters, SBIR Administrator, CDC (jvw0@cdc.gov) or 770-488-2805.

NATIONAL CENTER FOR ENVIRONMENTAL HEALTH (NCEH)

NCEH will accept SBIR applications ONLY on the August 1 and December 1, 2001 receipt dates.

The National Center for Environmental Health works to provide national leadership, through science and service, that promotes health and quality of life by preventing or controlling those diseases, birth defects, disabilities, or deaths that result from interactions between people and their environment. NCEH directs programs to

prevent the adverse health effects of exposure to toxic substances and to combat the societal and environmental factors that increase the likelihood of exposure and disease. NCEH main activities:

A. National leadership in prevention programs, global health, and the use of human genetic knowledge, tests, and services

B. Public health surveillance

C. Applied research: epidemiologic studies; laboratory analyses; statistical analyses; behavioral interventions; operations and systems research

D. Communication and education

E. Standards, guidelines, and recommendations

F. Training and technical assistance of officials of state and local health agencies in preventing and responding to public health challenges

The NCEH areas of interest focus on:

Environmental Hazards and Health Effects

A. Noise-Induced Hearing Loss in Children and Young Adults

B. Household Exposures to Hazardous Substances

C. Nutritional Supplements. Development of databases for identifying trends in the type, purchase, and/or use of nutritional supplements.

D. Prevention of Heat-Related Deaths Among the Elderly

Emergency and Environmental Health Services

A. Geographic Information System (GIS) Based Population Estimation and Sampling Software for Natural Disasters and Complex (Refugee) Emergencies

B. Consolidation of Guidelines and Recommendations Regarding Health and Public Health in Humanitarian Emergencies

C. Rapid Extraction Device for Chemical Mass Casualties

Environmental Health Laboratory Sciences

A. Coronary Heart Disease.

B. Cystic Fibrosis and Medium Chain Acyl Dehydrogenase Deficiency.

C. Tests for Type 1 Diabetes Associated Autoantibodies.

D. Enhancement of Blood Glucose Meters to Improve Management of Diabetes

E. Rapid Field Tests for Vitamin A Status

F. Rapid Field Tests for Iodine Levels in Urine and Salt

G. Rapid Field Tests or Continuous Monitors for Arsenic in Drinking

H. Rapid Field Tests for Iron Deficiency, Iron Deficiency Anemia, and Hemochromatosis

I. Improved Tests for Zinc Status and Zinc Body Stores in Humans

J. Environmental Health/Anti-Chemical Terrorism

K. Improving Assessment of Children's Exposure to Toxic Substances

For examples of areas of interest, see NCEH Topics.pdf.

Other Research Topic(s) Within Mission of Center

For additional information on research topics, contact:

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National Center for Environmental Health
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For administrative and business information, contact:

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FOOD AND DRUG ADMINISTRATION (FDA)

FDA will now accept SBIR grant applications on the same schedule as NIH—April 1, August 1, and December 1, 2001.

The mission of the Food and Drug Administration (FDA) is to protect the public health of the Nation as it may be impaired by foods, drugs, biological products, cosmetics, medical devices, ionizing and non-ionizing radiation-emitting products and substances, poisons, pesticides, and food additives. FDA's regulatory functions are geared to insure that foods are safe, pure, and wholesome; drugs, medical devices, and biological products are safe and effective; cosmetics are harmless; all of the above are honestly and informatively packaged; and that exposure to potentially injurious radiation is minimized.

For additional information about areas of interest to the FDA, please visit our home page at http://www.fda.gov.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

CBER is responsible for ensuring the safety, efficacy, potency and purity of biological and related products intended for use in the treatment, prevention or cure of diseases in humans as well as the safety of the nation's supply of blood and blood products. The primary responsibility of CBER is to review the quality, safety and efficacy of vaccines, blood products, certain diagnostic products and other biological and biotechnology-derived human products. For examples of areas of interest, see FDA Topics.pdf.

CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

CDER develops FDA policy with regard to the safety, effectiveness, and labeling of all drugs for human use; evaluates new drug applications and investigational new drug applications; develops standards for the safety and effectiveness of all over-the-counter drugs; monitors the quality of marketed drugs through product testing (bioavailability/bioequivalence testing), post marketing surveillance, and compliance programs; develops guidelines on good manufacturing practices; conducts research and develops scientific standards on composition, quality, safety, and efficacy of human drugs.

Drug regulatory research as conducted in CDER is directed at the discovery of new knowledge relevant to drug development, postmarketing drug experience (patterns of drug use and safety), and drug regulation to enhance FDA regulatory decisions. These drug regulatory decisions impact on the development of regulations, guidelines and guidance for the regulated industry and provide clarity and consistency in application of CDER regulatory requirements. These drug regulatory decisions also impact public health by ensuring that marketing drugs are safe and efficacious and that their risk benefit profile remains acceptable during the market life of a drug. Specific areas of research conducted by the Center include: Pharmacology/toxicology, microbiology/virology, clinical pharmacology, pediatric issues in drug therapy, postmarketing drug safety, evaluation of effectiveness of regulatory actions, patterns of drug use, including off-label, signal detection methodologies (e.g., datamining techniques), epidemiologic studies of therapeutics using population-based data, regulatory compliance, product quality, and active surveillance methods. For examples of areas of interest, see FDA Topics.pdf.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

CFSAN conducts research and develops standards on the composition, quality, nutrition, and safety of foods, food additives, colors, and cosmetics; conducts research designed to improve the detection, prevention, and control of contamination that may be responsible for illness or injury conveyed by foods, colors, and cosmetics; coordinates and evaluates FDA's surveillance and compliance programs relating to foods, color, and cosmetics; reviews industry petitions and develops regulations for food standards to permit the safe use of color additives and food additives; collects and interprets data on nutrition, food additives, and environmental factors affecting the total chemical result posed by food additives; and maintains a nutritional data bank.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

CDRH develops FDA policy and solves problems related to public health and safety of medical devices and radiation-emitting electronic products. It evaluates applications for premarket approval of medical devices, approves products development protocols and exemption requests for investigational devices. It classifies devices into regulatory categories, develops safety and effectiveness standards and good manufacturing practices regulations, operates postmarket surveillance and compliance programs, and provides technical, non-financial assistance to small manufacturers. The Center also conducts programs to reduce human exposure to hazardous ionizing and non-ionizing radiation, through an electronic product radiation control program and other programs designed to control and to limit radiation exposure. The Center develops and conducts research and testing programs in the areas of physical, life, and engineering sciences related to the human health effects of radiation and medical device technologies, provides expertise and analyses for health-risk assessments, and also develops new or improved measurement methods, techniques, instruments and analytical procedures for evaluating product performance and reliability. The overall research program may be categorized into four areas, as follows:

1. Characterization of the constituents or components of products.
2. Measurement of product performance.
3. Bioeffects that derive from human exposure to radiation or medical devices.
4. Radiation metrology in support of Agency regulation of radiation-emitting products.

For examples of areas of interest, see FDA Topics.pdf.

CENTER FOR VETERINARY MEDICINE (CVM)

CVM is a public health organization that enables the marketing of effective drugs, food additives, feed ingredients, and animal devices that are safe to animals, humans, and the environment. The Center, in partnership with Federal and state agencies and other customers, ensures animal health and the safety of food derived from animals. The Center makes timely, quality decisions and takes regulatory actions to ensure that these products provide for quality health care of animals, minimize the transmission of zoonotic diseases, and increase the efficiency of production of animal-derived food and fiber. Regulatory decisions are supported by research, the monitoring of product safety, and efficacy, and the continual improvement of processes. Emphasis is on: (1) development of analytical methods and animal models for animal drug residues in edible tissues and feeds, and (2) development of in vitro and in vivo models for evaluating the safety and efficacy of animal drugs.

OFFICE OF ORPHAN PRODUCTS DEVELOPMENT

The Office of Orphan Products Development was established to identify and facilitate the development of orphan products. Orphan products are drugs, biologics, medical devices and foods for medical purposes, which are indicated for a rare disease or condition (i.e., one affecting fewer than 200,000 people in the United States). These products may be useful in a rare disease/disorder but lack commercial sponsorship because they are not considered commercially attractive for marketing. A subcategory of orphan products are those marketed products in which there is evidence suggesting usefulness in a rare disease/disorder but which are not labeled for that disease/disorder because substantial evidence of safety and effectiveness for that use is lacking. For examples of areas of interest, see FDA Topics.pdf.

Other Research Topic(s) Within Mission of FDA

For additional information on research topics and administrative and business information, contact:

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